Improving outcomes in older vascular surgical patients

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Abstract

Older people commonly develop conditions that require definitive management with emergency or planned surgical procedures. Adverse postoperative outcomes are more common in these older patients in comparison to younger cohorts. This can be attributed in part to the pathophysiological profile of older people, who often present for surgery with coexisting physiological decline, multimorbidity and geriatric syndromes. The risk factors for vascular disease may put the vascular surgical population at particularly high risk of adverse postoperative outcomes. Preoperative Comprehensive Geriatric Assessment (CGA) and optimisation has not yet been studied in vascular surgical patients as a method to improve postoperative outcomes.

The overall programme of research presented in this thesis aims to design and evaluate an intervention to improve postoperative outcomes in older vascular patients, according to the Medical Research Council framework for 'Developing and Evaluating Complex Interventions'.

First, a systematic review and narrative synthesis of existing literature found that preoperative CGA and optimisation may improve postoperative outcomes in older patients undergoing elective surgery.
Second, a national UK wide survey identified only three trusts providing CGA and optimisation-based input throughout the perioperative pathway for older surgical patients. Geriatricians who responded to the survey cited funding and workforce issues as the main barriers to developing such services.
Third, an observational study described a high prevalence of frailty and cognitive impairment in older vascular surgical patients and showed that the combination of frailty and cognitive impairment contributes to postoperative morbidity and length of hospital stay. The use of brief assessment tools was shown to be acceptable and feasible in the preoperative setting in this study.
Fourth, a randomised controlled trial demonstrated that preoperative CGA and optimisation reduced length of stay in older patients undergoing vascular surgery by 40% when compared with standard preoperative assessment. This was predominantly due to fewer medical complications with a trend towards fewer delayed discharges.
Finally, an observational study described distress related to postoperative delirium in patients and their relatives. The degree and recall of distress was found to be associated with the severity of delirium and specific phenotypic features of the delirious episode.

In conclusion, the work presented in this thesis demonstrates that postoperative outcomes for older vascular surgical patients can be improved using a CGA based intervention. This programme of research sets the scene for ongoing work to further investigate patient reported postoperative outcomes and to study the implementation of CGA based perioperative services on a wider scale.

Contents

List of tables

List of publications from this thesis

J. S. L. Partridge, D. Harari, F. C. Martin and J. K. Dhesi. The impact of pre-operative comprehensive geriatric assessment on postoperative outcomes in older patients undergoing scheduled surgery: a systematic review. Anaesthesia. 2014 Jan;69 Suppl 1:8-16.

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Partridge JSL, Harari D, Dhesi, J. Frailty in the older surgical patient: a review. Age Ageing 2012; 41 (2): 142-7.

Glossary of Abbreviations

NHS	National Health Service
DSM 5	Diagnostic Statistical Manual 5
MCI	Mild Cognitive Impairment
MoCA	Montreal Cognitive Assessment
MMSE	Mini Mental State Examination
POD	Postoperative Delirium
POCD	Postoperative Cognitive Dysfunction
LTCI	Long Term Cognitive Impairment
CAM	Confusion Assessment Method
4AT	Rapid brief delirium assessment tool
CGA	Comprehensive Geriatric Assessment
EFS	Edmonton Frailty Scale
TUG	Timed up and go
MRC	Medical Research Council
BGS	British Geriatrics Society
PPI	Patient and Public Involvement

Appendices

[1] Montreal Cognitive Assessment

[2] Edmonton Frail Scale

[3] Partridge JSL, Harari D, Dhesi, J. Frailty in the older surgical patient: a review. Age Ageing 2012; 41 (2): 142-7.

[4] National UK geriatric medicine leads survey tool

[5] Participant information sheet - observational study

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[8] Consultee assent form - observational study

[9] Participant information sheet - CGA intervention randomised control trial

[10] Participant consent form - CGA intervention randomised control trial

[11] Consultee information sheet - CGA intervention randomised control trial

[12] Consultee assent form - CGA intervention randomised control trial

[13] Protocol for preoperative assessment and optimisation of cardiac issues

[14] Protocol for preoperative assessment and optimisation of anaemia

[15] Protocol for preoperative assessment and optimisation of delirium risk

[16] Protocol for preoperative assessment and optimisation of frailty

[17] Delirium distress questionnaire - patient participants

[18] Delirium distress questionnaire - relative/carer participants

[19] Participant information sheet - delirium distress observational study

[20] Participant consent form - delirium distress observational study

[21] Consultee information sheet - delirium distress observational study

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Chapter 1 - Background and literature review

1.0 The older surgical population

Atherosclerotic, degenerative and malignant pathology are conditions of older age and hence are increasingly observed as the population ages [1]. Many of these conditions require surgical management whether intended for symptomatic relief or to achieve cure. Despite the symptomatic and life protracting benefits seen for older patients undergoing surgery, this group remain at an increased risk of adverse postoperative outcome when compared to younger people [2].

These adverse postoperative complications can be considered under three main headings; clinician reported outcomes, patient reported outcomes and process measures including health system performance measures.

Clinician reported outcomes are the traditional measure of surgical success and are usually divided into rates of postoperative morbidity and mortality. Postoperative thirty-day morbidity and mortality rates have been published for many years but increasingly these measures are now reported at one or five years following surgery. Whether at the 30-day mark or at longer term follow up, higher rates of postoperative morbidity and mortality are seen in older patients across all surgical specialities [2]. Interestingly though, this higher postoperative morbidity rate is explained by medical as opposed to surgical issues. For example, the rate of anastomotic leak recorded in a large study of those undergoing colorectal resection remained static as age increased, whereas the frequency of cardiac, pulmonary, renal and thromboembolic complications following surgery was progressively higher with increasing age [3].

Similarly, rates of graft failure or wound infection are equivalent between cohorts aged under and over 80 years undergoing lower limb arterial revascularisation with the observed excess of postoperative morbidity in the over 80 year olds instead resulting from cardiac, respiratory and renal complications [4]. Such findings have been replicated in various surgical groups. These postoperative medical complications are particularly relevant, as they are independent predictors of both short term (30 day) and longer term postoperative mortality (up to five years)[5 6].

Patient reported outcomes are also worse in older patients compared to younger people following surgery. These include postoperative cognitive decline [7] and impaired functional status, with a failure to recover to preoperative levels of activity, all of which influence quality of life measures. For example, after major surgery including abdominal and vascular procedures, several measures of functional status including activities of daily living, functional reach, timed walk and grip strength remained impaired up to six months after surgery in older people [8]. In older patients undergoing cardiac surgery cognitive deterioration following delirium is commonly observed [9].

These adverse clinician and patient related outcomes in turn impact on process measures such as length of hospital stay, need for rehabilitation or increased level of care at hospital discharge, all of which incur greater financial cost. The financial burden results from direct costs in bed days or social care input but also from indirect costs such as loss of earnings in family members who assume caring roles. Although the older surgical patient has consistently been shown to experience an excess of postoperative morbidity and mortality incurring increased financial cost [10], it is not

chronological age per se which is solely responsible. Instead the risk profile for adverse postoperative outcome observed with older age is thought to be due to three factors.

First, age related physiological change which is observed across all organ systems [11]. Examples include increased arterial stiffness and cardiac fibrosis in the ageing heart, a decrease in vital capacity and respiratory muscle strength in the respiratory system and a gradual decline in glomerular filtration rate in the renal system. Age related physiological changes especially in the cardiac and respiratory systems, even in the absence of pathology, are associated with increased perioperative complications [12].

Second, the accumulation of not just comorbidity but multimorbidity. Defined as the coexistence of two or more comorbidities, multimorbidity is increasingly recognised as an independent predictor of postoperative complications [13]. Twenty three percent of the adult primary care population were defined as multimorbid in a study examining patients registered at general practices in Scotland [14] and by the age of 65 years most were defined as multimorbid. The influence of socioeconomic deprivation is also increasingly recognised, with this study showing that those living in deprived areas were more likely to be multimorbid, until the prevalence equalised at the age of 85 years.

Third, the increasing presence of geriatric syndromes with advancing age. Geriatric syndromes are those conditions which lack a defined aetiology but which share a set of phenotypic expressions and include falls, incontinence, delirium, mobility impairment

and frailty. Frailty, in particular, is independently associated with adverse postoperative outcome and will be considered in more detail in section 1.4.

Despite the fact that these risk factors for adverse postoperative outcome have been well described in the academic literature, it is only relatively recently that a series of national UK reports have highlighted failings in care for older surgical patients with these factors in mind. In 2010 the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report 'An Age Old Problem', described a lack of proactive identification of comorbidity, significant levels of disability and frailty and an overreliance on 'on-call' medical staff providing medical input, resulting in adverse outcomes for older surgical patients [15]. Furthermore, a series of joint reports produced by the Royal College of Surgeons, Age UK, The Dunhill Medical Trust and MHP Health Mandate in 2012, 'Access all Ages 1 and 2', concluded that older patients are denied equitable access to surgery when compared to younger people with similar disease processes [16 17]. The Royal College of Surgeons report 'The High Risk Surgical Patient', concurs with the findings in 'An Age Old Problem' and 'Access all Ages' and advocates routine daily involvement of geriatricians in the care of older surgical patients [18]. Intuitive though this may sound, within the UK NHS such proactive structured and funded geriatric medicine input does not currently exist in most hospital trusts. Certainly, the findings of these reports have prompted a national dialogue about collaborative working between physicians, anaesthetists and surgeons, about optimal models of care required to deliver such structured geriatric medicine input in the perioperative setting and regarding workforce planning issues were such services established nationwide. The literature informing these discussions will be considered

in more detail in chapters 2 and 3, but to date the lack of evidence underpinning proactive structured geriatric medicine input in the surgical pathway of care has been a limitation to the widespread development of services.

1.1 The older vascular surgical patient

Within vascular surgery the expansion of the older population has prompted advances in surgical techniques better suited to a frailer more vulnerable group [19]. For example, less invasive approaches for repairing abdominal aortic aneurysms has led to endovascular surgery being undertaken in those who may not be able to withstand the stresses of an open procedure [20]. Whilst such developments are key in reducing the adverse impact of surgery on the older population, the specific medical and age-related issues within the vascular surgical population are yet to be fully described and addressed as they have been, for example, in older hip fracture patients.

The risk factors for atherosclerotic vascular pathology include older age, smoking, lack of exercise or sedentary lifestyle, hypertension, hypercholesterolemia, and diabetes [21]. Whilst a combination of these lifestyle and comorbid conditions can cause lower limb arterial occlusion, they can also result in vascular stenoses and occlusion at different sites for example coronary or cerebral lesions. This was studied by the REduction of Atherothrombosis for Continued Health (REACH) registry that enrolled patients with existing peripheral, cerebrovascular or coronary arterial disease or risk factors for arterial disease. At two year follow up 41% of patients with stroke or Transient Ischaemic Attack (TIA) had disease in other territories (30% coronary artery disease, 5% symptomatic peripheral arterial disease and 6% both coronary artery disease and

peripheral arterial disease)[22]. If those without symptoms of peripheral arterial disease but with a low ankle brachial pressure index indicative of lower limb arterial disease were included, the frequency of concomitant stroke or TIA and peripheral arterial disease rose to over a third [23]. Furthermore, asymptomatic peripheral arterial disease is known to have an equivocal risk factor profile, pattern of comorbidity and similar mortality to symptomatic disease [24]. In addition, risk factors for arterial disease also predispose to vascular cognitive impairment and frailty which will be considered in sections 1.2 and 1.4.

Given this profile of multimorbidity and geriatric syndromes, the patterns of health care usage in the older vascular surgical population are of interest. The nature of lower limb arterial disease and the variety of approaches to managing this condition leads to a patient pathway which is different from that encountered in other surgical groups. For example, in elective orthopaedic surgery, patients often present once for a joint replacement and do not require multiple subsequent readmissions under the same surgical speciality. In contrast the progressive nature of peripheral vascular disease together with the frequently encountered issues with infected ulcers, graft restenosis and multisite disease can often result in frequent readmissions for this older surgical group. Given that hospitalisation can be considered a significant event for the older, frail patient with inherent risks of delirium, deterioration in functional status and hospital acquired infections, the concept of geriatric medicine co-management may seem attractive. Such collaborative care would offer an opportunity to address the often ‘missed opportunity’ for health promotion advice and medical optimisation with

the potential to modify short term perioperative outcomes but also impact on longer term outcomes [25].

1.2 Specific issues - neurocognitive disorders

As the population ages, neurocognitive disorders are progressively observed. The Diagnostic and Statistical Manual (DSM-5) refers to major neurocognitive disorder or dementia and minor neurocognitive disorders or mild cognitive impairment. The definitions of these conditions are shown in table 1.

Table 1 - Diagnostic and Statistical Manual 5 (DSM 5) classification of major and minor neurocognitive disorders

	Major neurocognitive disorder (dementia)	Minor neurocognitive disorder (mild cognitive impairment)
Patient, informant or clinician report evidence of cognitive decline across one or more neurocognitive domains	Substantial decline	Modest decline
Objective decline in neurocognitive function on assessment	2 or more standard deviations below appropriate norms	1-2 standard deviations below appropriate norms
Impacts on activities of daily living such that no longer fully independent	Yes	No
Not attributable to delirium or other mental health disorder	Yes	Yes

Those with mild neurocognitive disorder or Mild Cognitive Impairment (MCI) have an increased risk of developing major neurocognitive disorder or dementia in the future especially when the domain of memory is predominantly affected. However not everyone diagnosed with MCI progresses to dementia. The overarching term

'neurocognitive disorder' does not differentiate between the many aetiological subtypes of dementia including Alzheimer's disease, Lewy body dementia, and vascular neurocognitive disorder amongst others. Risk factors for vascular disease such as those considered previously in section 1.1 are also independent risk factors for both vascular type neurocognitive disorder and Alzheimer's disease [26]. The relationship between vascular risk factors, cerebral blood vessel changes, medical risk factor control and the potential impact on both vascular dementia and Alzheimer's dementia is not yet fully understood but remains a subject of ongoing research.

The relevance of neurocognitive disorders in the perioperative setting

Despite these unknowns, it is observed that as the population ages the prevalence of neurocognitive disorders increases, with an estimated frequency of 10% of those aged over 65 years having Alzheimer's dementia. A study conducted within older patients undergoing elective orthopaedic surgery showed that 22% had previously undiagnosed amnestic MCI or minor neurocognitive disorder [27]. Although not previously documented, it could be postulated that this would be higher still in the older vascular surgical population due to the presence of vascular risk factors which would predominate less in those with osteoarthritis requiring joint replacements.

This is important for several reasons. First, the UK National Dementia Strategy (2009) advocates the early diagnosis of cognitive impairment and dementia in order to ensure those with these conditions can be fully supported with medical intervention and support services from the start of their illness [28]. This clearly has implications for a group known to be at high risk, the vascular surgical population. Second, undiagnosed cognitive impairment has a potential impact on the process of informed consent

crucial to shared decision making within the perioperative period. Third, the likely considerable undiagnosed burden of vascular cognitive impairment and vascular dementia within this patient group confers an increased risk of postoperative delirium which will be discussed further in section 1.3. Fourth, cognitive impairment is known to have implications on longer term postoperative outcomes including rehabilitation potential and functional recovery. Literature reflects the often 'missed opportunity' for medical optimisation within this population with potential short term perioperative implications but also potential longer term consequences.

Assessment of neurocognitive disorders

As illustrated in table 1 the diagnosis of either major or minor neurocognitive disorder relies on the combination of self or observer reported cognitive decline and objectively impaired cognition evaluated using neurocognitive assessment. Different methods of cognitive assessment exist, ranging from full neurocognitive assessment batteries which take several hours to complete, to brief cognitive assessment tools. The benefits and drawbacks of these assessment tools depend on the environment in which they are being used. For example, a full neurocognitive assessment battery may be appropriate in a memory clinic service where each patient is allocated a three hour appointment time and a neuropsychologist is present to undertake the evaluation. This tool however would not be suited to the acute hospital setting where patients may need more rapid cognitive assessment prior to undertaking a surgical procedure. Whilst in this scenario a briefer cognitive assessment tool would be more suitable, consideration should also be given to the properties of the brief assessment tool, including how effectively it examines the type of cognitive impairment that is

anticipated, whether it is appropriate to the educational level of the population and whether it adequately evaluates sufficient cognitive domains. For example, in a vascular surgical population where executive dysfunction attributed to vascular neurocognitive disorder is likely to be frequently encountered, choosing the Montreal Cognitive Assessment (MoCA) (appendix 1) in place of the Folstein Mini Mental State Examination (MMSE) as a brief assessment tool, may be more appropriate as the MoCA better evaluates executive functioning.

The impact of cognitive impairment on risk of postoperative delirium is of particular relevance to this thesis. Within the academic literature the terms postoperative delirium (POD), postoperative cognitive dysfunction (POCD) and longer term cognitive impairment (LTCI) have all been used. Whilst the focus in this thesis is on POD the debate about potential causation and overlap between these conditions will be first considered in 1.3.

1.3 Specific issues - delirium

Delirium is defined by the DSM 5 criteria as a condition of acute onset and usually fluctuating course characterised by a disturbance in attention, awareness and cognition attributable to an underlying cause and not solely due to coma. In the case of postoperative delirium (POD) this underlying trigger is often a surgical procedure but may also result from postoperative medical morbidity including sepsis, constipation, electrolyte disturbances or pharmacological triggers, including opiate analgesia amongst others. The gold standard for diagnosis uses this set of criteria in the hands of an experienced clinician for example, a consultant psychiatrist or

geriatrician. Various tools have been developed in order to aid screening and diagnosis. These include the 4AT [29] for screening and the diagnostic tool, Confusion Assessment Method (CAM) [30] amongst others.

Postoperative cognitive dysfunction (POCD)

In comparison, postoperative cognitive dysfunction (POCD) has to date been less clearly defined leading to issues in interpreting the research in this field. Broadly speaking POCD is described as neurocognitive change persisting beyond the immediate postoperative period but definitions vary between studies. In general, a neurocognitive assessment battery is performed preoperatively and then at various predefined time periods postoperatively and a comparison is made with non-operative controls. POCD is said to have occurred if the postoperative neurocognitive assessment scores of the surgical subjects have deteriorated by 1.5-2 standard deviations below the mean.

Postoperative cognitive dysfunction (POCD) and postoperative delirium (POD)

The lack of a universally accepted definition of POCD has resulted in difficulties comparing the frequency, aetiology, triggers and overlap between POD and POCD. One of the main issues limiting the interpretation of the literature has been the lack of emphasis on diagnosis of delirium in studies observing POCD. For example, in the International Study of Post-Operative Cognitive Dysfunction (ISPOCD) approximately a quarter of patients were observed to score <2.5 standard deviations below the mean on a neurocognitive battery performed just prior to and within a week after non-cardiac, non-neurological surgery [31]. In the absence of a measure of delirium in the

initial postoperative period, labelling the deterioration in cognition observed in this quarter of patients as POCD is contentious as it may well have been delirium. Furthermore, the lack of a widely accepted definition of POCD has led to discrepancies in the cited incidence of the condition which vary widely from 5-50 % [7]. Other limitations to research in POCD include the frequent omission of a control group making the deterioration in cognitive trajectory observed after surgery difficult to solely attribute to the surgical episode. If no deterioration was seen in an age, gender and morbidity matched control group not subjected to surgery under anaesthesia, drawing conclusions about causality would be more robust. Similarly, the published work in this area is hampered by a limited understanding of the cognitive trajectory of patients prior to surgical procedure under anaesthesia, which clearly has bearing on predicting the postoperative trajectory. Finally, as we understand more about the impact of delirium on worsening an already deteriorating cognitive trajectory, an argument can be made that POD and POCD may in fact be different terms for the same condition.

Postoperative delirium (POD)

Having acknowledged the issues with the available literature in this field the focus of the remainder of this section will now be on delirium. Postoperative delirium is common occurring in about a third of those following hip fracture repair [32]. In vascular surgery it most commonly occurs after open aortic aneurysm repair [33]. Whilst the advent of less invasive endovascular surgical techniques may result in a lower incidence of delirium, the ageing population and presence of vascular risk factors suggest that delirium will remain a significant potential postoperative complication in

those undergoing vascular surgery. Table 2 shows the predisposing and precipitating risk factors for the development of delirium [34].

Table 2. Predisposing and precipitating risk factors for the development of delirium

Predisposing factors	**Precipitating factors**
Age	Sepsis
Dementia or cognitive impairment	Acute illness (e.g. MI)
History of delirium	Untreated pain or excess use of analgesics
Severe illness or hip fracture	Urinary retention
Malnutrition/dehydration	Constipation
Polypharmacy	Loss of sensory aids/clues
Sensory impairment	Sleep deprivation
Functional dependency	Change in environment
Depression	Physical restraints

Pathophysiology of delirium

The pathophysiology of delirium remains incompletely understood. However, the following are known to contribute, although not necessarily in each case, assuming that there are a range of pathophysiological routes to the end result, delirium [35];

- Cytokine dysregulation especially involving interleukin 1 and 2, Tumour Necrosis Factor α and interferon

- Changes in neurotransmitter expression especially cholinergic deficiency, dopaminergic excess with other neurotransmitters including noradrenaline, serotonin, gamma-aminobutyric acid, glutamate and melatonin also implicated
- Diffuse slowing of cortical activity
- Chronic hypercortisolism

Clinical features of delirium

Delirium can present with different clinical subtypes related to the timing of onset of the condition and the phenotypic expression. The National Institute for Health and Care Excellence (NICE) describes incident and prevalent delirium based on the timing of the onset [32]. Prevalent delirium is detected at clinical presentation for example in a patient with critical limb ischaemia and resultant sepsis presenting to the emergency department. In contrast incident delirium occurs over 24 hours into a hospitalisation for example in a patient undergoing elective open abdominal aortic aneurysm repair who is not delirious at the point of planned hospital admission but who develops POD following surgery. Clinically, patients with delirium can either present as drowsy and withdrawn, termed hypoactive delirium, or can be agitated with behavioural manifestations such as aggression or wandering. This latter subtype is termed hyperactive delirium. A third and common phenotype, mixed type delirium, occurs when patients display both hypoactive and hyperactive features at differing times during the course of the illness. More recently subsyndromal delirium has also been described and is frequently observed in care home populations. This is defined as a partially resolved or incomplete form of delirium [36].

Impact of delirium

Across all clinical subtypes the impact of delirium in terms of increased morbidity, mortality and higher rates of institutionalisation at hospital discharge is clear [37]. The psychological implications of delirium are less well described but are increasingly being researched. Delirium related distress has been reported in ICU survivors, medical and surgical patients, those undergoing cancer treatments and in terminal care populations. This will be considered in more detail in chapter 6. Furthermore, although traditionally described as a reversible phenomenon delirium is increasingly understood to have longer term permanent cognitive sequelae. This significant longer term impact of delirium makes attempts at preventing the condition paramount.

Reducing the occurrence of delirium

The literature examining the prevention of delirium divides broadly into pharmacological interventions and complex multicomponent interventions. Although several pharmacological interventions have been trialled in medical, surgical and intensive care populations to date, none of these have yet been proven to reduce the incidence of delirium [38]. In contrast, multicomponent interventions targeting the precipitating factors for delirium (table 2) have a robust evidence base in preventing delirium in older medical and surgical patients [38]. The exact multicomponent intervention varies slightly between studies, but in all cases attempts to address the precipitating factors for delirium are delivered in a systematic manner. Such multicomponent delirium prevention strategies have reduced the delirium incidence from 15-9.9% in medical patients [39] with similar reductions seen in hip fracture patients (50% delirium incidence in control group versus 32% delirium incidence in

intervention group) [40]. An example of such a targeted multicomponent intervention addressing the risk factors for delirium is given in table 3.

Although these multicomponent interventions have been shown to impact favourably on delirium incidence in the academic literature, translation into routine clinical care can lack fidelity to the evidence based intervention producing inconsistent results. Having considered the geriatric syndromes of cognitive impairment and delirium, the geriatric syndrome of frailty will be considered next.

Table 3. Multicomponent interventions to reduce incidence of delirium.

Precipitating factors	**Modification**
Sepsis	Prevent through usual measures (removal of IV lines and catheters, early ambulation and self-directed breathing exercises etc.) Early identification and treatment according to national guidelines
Acute illness (e.g. MI)	Medical optimisation of risk factors to ensure prevention Early identification and treatment according to national guidelines
Untreated pain or excess use of analgesics	Proactive pain management using opiate sparing agents where possible and incorporating use of nerve catheters, neuraxial blocks as needed
Urinary retention	Preoperative assessment of known or undiagnosed BPH Pharmacological management of benign prostatic enlargement Minimise unnecessary urinary catheterisation Trial without catheter as soon as possible
Constipation	Proactive management of constipation and avoidance where possible of constipating agents
Loss of sensory aids/clues	Ensure patients wearing glasses and hearing aids Use orientation boards and large clocks
Sleep deprivation	Promote usual day night routine – sit out and exercise in the day, make wards quiet and dark, use melatonin as needed to promote sleep
Change in environment	Admit morning of surgery where possible Avoid unnecessary ward moves
Physical restraints	Avoid use of physical restraint wherever possible using de-escalation techniques and 1:1 nursing as needed

1.4 Specific issues - frailty

Frailty is a state of increased vulnerability to poor resolution of homoeostasis after a stressor event, which increases the risk of adverse outcomes [41]. It occurs commonly but not universally as age increases, with estimates that between a quarter and a half of over 85 year olds are frail [42 43]. Whilst this constitutes a significant proportion of the older population who are at markedly increased risk of falls, limited functional status, long term care and death, it equally means that up to three quarters of over 85 year olds are not frail. This raises questions about the accurate identification of frailty, particularly in the early stages, and the aetiology and potential modifiers of the syndrome.

Models of frailty

Two models of frailty have been described. The first of these, the frailty phenotype was developed through secondary analysis of data from the Cardiovascular Health Study [42]. The frailty phenotype proposes five variables; unintentional weight loss, self-reported exhaustion, low energy expenditure, slow gait speed, and weak grip strength and describes individuals with three or more of these variables as frail, those with one or two factors present as pre-frail and those with none of the variables as 'robust'. Adverse outcomes including seven year mortality were progressively more frequent as the degree of frailty increased.

The frailty index or deficit accumulation model of frailty was derived from the Canadian Study of Health and Aging using 92 variables including symptoms, signs, existing diagnoses and biochemical markers [44]. The index uses a binary count of the

absence or presence of each variable in an individual and thus calculates the number of accumulated deficits from the total possible deficit count, giving a result on a continuous scale from 0 (least frail) to 1 (most frail). The more deficits, the frailer the individual and the higher the risk of institutionalisation and death. In this original description of the frailty index, by the time the index reached about 0.67, further deficit accumulation seemed impossible and death resulted. The index has been replicated using different sets of variables producing similar results providing the measures collected represent multiple domains. Furthermore, the index has also been derived using a count of 30 potential deficits as opposed to the original 92. Such an approach using fewer variables appears valid provided the spread of variables collected is multidomain and the nature of the subdomains are specific, for example, they must be prevalent, must progressively be observed with increasing age and must plausibly contribute to death.

Pathophysiology of frailty

The aetiology of both ageing and frailty are complex and incompletely understood involving genetic and environmental factors in combination with epigenetic mechanisms. Inflammatory cytokines, advanced glycation end products produced through the glycation of proteins, lipids and nucleic acids, changes to Insulin-like Growth Factor signalling, sex hormone production and cortisol secretion are all thought to be important in causing frailty. These mechanisms result in age related changes across all organ systems with frailty occurring once the cumulative decline renders the individual sufficiently vulnerable that a relatively minor external stressor results in a disproportionate deterioration in health or functional status [41].

Impact of frailty

Regardless of the model studied or the incomplete understanding of the aetiology of the syndrome, frailty is associated with a higher chance of falls, worsening disability, hospitalisation, care home admission and death [42]. In very frail individuals even a seemingly insignificant external insult such as a minor infection, new medication or day case surgical procedure can result in profound physical, functional or cognitive deterioration, often such that the threshold between dependence and independence is crossed. For example, an older person with dementia and frailty managing independently at home, who develops a viral chest infection, may rapidly become cognitively dependent due to delirium and physically or functionally dependent necessitating the provision of care.

Within the surgical population aged over 18 years, frailty is common occurring in up to 50% of patients undergoing planned procedures. Results from a literature review conducted in preparation for this thesis, demonstrate that regardless of the surgical population (subspecialty, elective or emergency presentation) or which frailty tool is used, frail patients consistently have increased rates of postoperative morbidity and mortality [45 46]. This raises questions about how to accurately measure frailty and whether frailty can be modified preoperatively. These issues will be examined in turn.

Identifying frailty

Numerous tools exist to identify and measure frailty. These tools vary in their utility depending on the setting in which they are used. For example, single measures of functional ability, strength or gait velocity are quick and easy to measure but may lack

sensitivity and specificity for frailty and will be unsuitable in some populations such as non-prosthetic limb-wearing amputees. Other tools may be complex and detailed referring to a particular patient group such as the Comprehensive Assessment Frailty score used in those undergoing cardiac surgery. Whist such tools may have utility in the research setting, they may be unfeasible in a busy clinical environment. The more recently developed Electronic Frailty Index uses variables routinely collected by large general practice databases to calculate a frailty index (as described in the Rockwood frailty model) and thus highlight those with frailty in the primary care setting [47]. Such a system may be extrapolated to other secondary care settings in the future. Another multidomain frailty tool used frequently in clinical practice is the Edmonton Frail Scale (appendix 2) [48]. Benefits of this scale include brevity, validation for use by non-geriatricians, normal distribution in the older population, reasonable interrater reliability, good internal consistency and the ability to highlight areas contributing to overall frailty that are potentially amenable to optimisation. A small study has demonstrated a good correlation between the Edmonton Frailty Scale (EFS) and a Clinician's Global impression of Frailty [48]. As with many other frailty tools however, diagnostic accuracy has not been fully investigated.

Modifying frailty

No evidence based single frailty modifier exists. Studies have examined pharmacological agents, exercise, nutritional supplementation and multicomponent interventions with limited success to date. Limitations to this body of work result from a lack of explicit frailty measures such that in many cases the findings are extrapolated from populations known to have a high prevalence of frailty for example care home

residents, hip fracture patients, sarcopenic subjects or those with pressure ulcers, but without frailty being explicitly defined or identified. Despite these acknowledged issues, no pharmacological interventions are currently supported by the literature, although there is support for the positive effect of angiotensin converting enzyme inhibitor medications on skeletal muscle function, testosterone on muscle strength and vitamin D on neuromuscular functioning. Side effects, in the case of testosterone and lack of convincing efficacy have limited the widespread use of these medications, although research into the use of angiotensin converting enzyme inhibitors as a therapeutic agent in those with sarcopenia is currently ongoing [49-51] .

Similarly, although the use of nutritional supplementation to slow or reverse the weight loss commonly associated with the frailty syndrome may seem therapeutically attractive, this has not yet been supported in research studies.

Exercise intuitively seems sensible in a group known to be largely sedentary with slow gait velocity and is known to have positive physiological effects on the brain, endocrine system, immune system, and skeletal muscle [41]. However, research examining the impact of exercise on modifying frailty is mixed, with suggestion that the most frail patients gain the least from this intervention [52]. This does not preclude clinicians from recommending exercise programmes for other indications and positive results may emerge in future trials.

Translation of this scant evidence on frailty modification into the preoperative setting, is even more problematic. Whilst the national appetite for prehabilitation exercise programmes in older, frail, surgical populations has been considerable, to date there is

no evidence linking these with improved postoperative outcomes. In vascular surgical populations where risk factors for arterial disease are common to the development of frailty, it is probable that frailty is a significant contributor to the observed postoperative complications (see appendix 3 for literature review examining frailty in the older surgical patient).

This leaves researchers and clinicians aware that frailty has an adverse impact on outcomes in community dwelling, medical and surgical hospital populations, able to identify the syndrome using various tools but unable to effectively treat frailty with a single intervention or modifier evidenced to have benefit. In this situation the role of multicomponent interventions to modify aspects of the frailty syndrome appear attractive. The established multicomponent intervention Comprehensive Geriatric Assessment (CGA) has been shown to have benefit on morbidity and mortality in older frailer patients and will be further considered in section 1.5 [53 54].

1.5 Comprehensive Geriatric Assessment and optimisation (CGA)

CGA and optimisation is an established method for evaluating and managing older patients in various different clinical settings. It involves a multidomain, interdisciplinary assessment aiming to describe both known pathology and previously undiagnosed conditions together with evaluating functional, psychological and social status. This multidomain assessment prompts the formulation of a short and longer term investigation and management plan for all issues identified. For example, medical management for known ischaemic heart disease may be uptitrated, a new diagnosis of COPD and anaemia made, investigated and treated and the patient may be offered

falls and balance training for falls risk whilst an occupational therapist evaluates and modifies the home environment. In another case a new diagnosis of dementia may be made and medications for pain commenced due to a failing revision hip replacement. Involvement of a community pharmacist could ensure a dosette box to improve medicines adherence and safety and the social worker could arrange a care package and referral to a dementia nursing team to support the patient and their family. Undergoing CGA as a hospital inpatient on a geriatric medicine unit has been shown to increase the chance that the older patient is alive and less likely to be admitted to a care home up to 12 months after the intervention [54]. Table 4 shows examples of how CGA can be used to preoperatively assess and optimise older people.

Table 4. Using CGA to preoperatively assess and optimise

Domain	Issue	History / examination	Screening or diagnostic tools	Investigation	Optimisation
Medical	Postural hypotension with visual hallucinations	History of falls Reports of 'slowing, falls, tremor, rigidity etc. Proactive assessment for non-motor symptoms if Parkinson's disease likely Physical examination	Unified Parkinson's Disease Rating Scale	DaTSCAN Cerebral imaging with computed tomography or magnetic resonance imaging (does not necessarily need to be preoperative)	In established cases – proactive plan around medications including timings and alternative drugs or routes of administration when nil by mouth Pre-emptive advice to ward teams about non-motor complications likely at time of surgery (constipation, delirium, falls) In newly identified cases consider starting medications preoperatively versus outpatient follow up based on symptoms and urgency of surgery
	Exertional dyspnoea and daily cough	Smoking history but no prior known chronic lung disease History of symptoms of Chronic Obstructive Pulmonary Disease	Medical research council breathlessness scale 6 minute walk test	Spirometry CXR	Smoking cessation advice Flu vaccination Inhaled therapy according to NICE/British Thoracic Society guidelines Pulmonary rehabilitation according to local guidelines
Geriatric syndromes	Falls	Previous history History of 'near misses', suggestive underlying causes, injuries sustained Bone health screening	Gait speed Timed up and go Fracture Risk Assessment Tool	Bone profile and Vitamin D Suggestion to GP about DEXA and follow up	Medical management of bone health (e.g. bisphosphate and Calcium vitamin D supplementation) Medical falls review Strength and balance training
	Cognitive impairment	Self-reported history of cognitive issues Collateral history from relative / carer	4AT MoCA	Cerebral imaging or recommendation to General Practitioner for this	Delirium risk assessment and optimisation e.g. cessation of anti-cholinergic medications, ensuring normal electrolytes, treating constipation Signposting to standardised postoperative management of delirium Communication with patient and relatives Long term vascular risk factor management Referral to memory services for long term follow up
Psycholog-ical	Anxiety and depression	Self-reported history Collateral from family/carer Symptoms	Hospital Anxiety and Depression Score	Thyroid function tests Exclusion of cognitive impairment	Referral for psychological support (talking services) Consider pharmacological treatment Explanation or counselling regarding surgery if this is prominent trigger for symptoms
Functional and social	Functional dependency	Self-reported concerns Collateral from family/carer Assessment of underlying cause	Barthel Nottingham Extended Activities of Daily Living	Physical examination and investigation of pathology causing disability e.g. proximal myopathy secondary to vitamin D deficiency Prescribe analgesia for osteoarthritis	Preoperative physiotherapy Occupational Therapy intervention (e.g. home adaptions) Social worker intervention to proactively identify barriers to discharge Proactive communication regarding anticipated length of stay and access to rehabilitation or care at discharge
	Non-adherence to prescribed medications	Self or family reported concerns Clinical evidence of non-adherence Assessment of understanding of medications	STOPP/START *(see optimisation box for explanation of acronym)*	Assessment of cognition and understanding of medications	Liaising with community pharmacist to assist with dosette box and with care services or telecare to prompt medication *STOPP: Screening Tool of Older People's potentially inappropriate Prescriptions* *START: Screening Tool to Alert doctors to Right Treatments*

CGA based orthogeriatric care

Given the high incidence of medical morbidity, frailty and poor outcomes following hip fracture the collaboration between orthopaedic surgery, anaesthetics and geriatric medicine has now been well established in the field of orthogeriatrics. Different models of care exist but the principle of proactive, preferably preoperative, geriatric medicine input with continuity throughout the hospitalisation is thought to be key. The evidence for CGA and optimisation delivered through orthogeriatric models shows a reduction in postoperative mortality, fewer discharges to an increased level of care, reduction in length of hospital stay and a reduction in financial cost [55]. Of note this Cochrane review of CGA in the surgical setting includes seven papers examining orthogeriatric care in patients with hip fracture in addition to a single study of CGA in those undergoing cancer surgery. This evidence in support of orthogeriatric models of care has led to the Department of Health in England enshrining the involvement of geriatricians in hip fracture pathways through an incentivisation process called the best practice tariff initiated in 2011. Following the introduction of this best practice tariff, improved clinical outcomes in terms of reduced mortality have been observed in this frail postoperative group [56]. In other surgical specialities collaboration between geriatricians, anaesthetists and surgeons is less well established. This is despite the fact that as discussed in sections 1.0 and 1.1 these surgical populations also have geriatric medicine needs. To date CGA has not been robustly trialled in surgical populations excepting those undergoing hip fracture surgery. In fact, in surgical and cancer populations, literature examining CGA is often limited by the sole use of the 'assessment' component of the process [57]. This tends to be used for prognostication or

definition of risk as opposed to triggering the 'optimisation' aspect of CGA, where the aim is to modify risk and thus improve outcomes.

1.6 Summary of literature and an underpinning methodological framework

In summary, it is evident that despite clear benefits for older people in undergoing surgery, they experience more postoperative medical complications than younger patients with a resultant impact on longer term functional outcomes. The older vascular surgical group may be at even higher risk than other surgical populations by virtue of the underlying risk factors for vascular disease including cigarette smoking and sedentary lifestyle. The impact of multimorbidity, neurocognitive disorders, frailty and delirium in the perioperative period is significant and well described by a series of prominent national reports. CGA and optimisation offers a potential modifier of these adverse outcomes.

Given the complex nature of CGA as an intervention, researching its impact can be problematic. The Medical Research Council (MRC) have produced guidance on 'Developing and Evaluating Complex Interventions' [58-60]. This guidance and the application of it to this thesis will be considered next.

1.7 Employing the MRC framework to evaluate the role of CGA and optimisation in the perioperative setting

Comprehensive Geriatric Assessment and optimisation is a complex intervention with several interacting components. Researching the impact of such interventions is inherently problematic with specific issues encountered in standardising the design

and delivery of the complex intervention, adapting interventions to the local context whilst maintaining fidelity, the additional complexity of coexistent service or policy change and the often long causal chains linking intervention with outcome.
In accordance with the MRC framework the following steps were taken in designing and undertaking this programme of work;

Reviewing the evidence base (addressed in objective [1])

The background literature review that underpins this programme of research has been presented in sections 1.0-1.5. In chapter 2 a systematic review of the literature examining the preoperative use of CGA and optimisation is presented.

Identifying or developing appropriate theory (addressed in objective [1])

Through the literature review process (chapters 1 and 2) the use of CGA and optimisation as an underpinning theoretical model was identified. This established methodology was chosen due to its impact on the potential outcomes (clinician reported and process outcomes) in addition to its suitability to the assessment and management of those with multimorbidity.

Modelling process and outcomes (addressed in objectives [2],[3],[4],[5],[6])

This stage of developing the research programme involved two main projects. First, an exploration of the existing use of CGA in the perioperative setting using survey methodology (chapter 3). Second, a full description of the medical and geriatric issues in the older vascular surgical population and the impact of these factors on process outcomes, was undertaken using an observational study (chapter 4). As part of the

design of this observational study, patient and public opinions were sought, in a process of co-design, in order to establish research outcome measures that were meaningful to all clinical and non-clinical stakeholders.

Identifying appropriate trial design in order to evaluate the complex intervention (addressed in objectives [6],[7])

Having scoped and defined the issues and potential intervention using observational research and patient and public co-design, a single site randomised controlled trial design was chosen to evaluate the impact of the complex multicomponent intervention of CGA and optimisation on the primary end point of hospital length of stay. This study is presented in chapter 5.

Implementation

The final stage of developing and evaluating complex interventions described within the MRC guidance is spread of implementation. Whilst this was beyond the scope of this research thesis the underpinning work described above and the dissemination of the study findings through publications and presentation has resulted in a substantive service at the study centre and set the scene for sustainable implementation of such services nationally.

1.8 Research aim and objectives

Based on this summary of the background literature, description of the evidence based intervention CGA and optimisation and reference to the MRC framework for evaluating complex interventions, the remainder of this thesis will address the following research aim and objectives;

Aim of thesis;

To more fully describe a specific older surgical population (those undergoing arterial surgery) in terms of clinician reported, patient reported and process outcomes and examine the services which already exist for these patients in order to design and evaluate an intervention to improve postoperative outcomes using established frameworks for evaluating complex interventions.

Objectives;

[1] To describe the literature examining whether preoperative CGA affects postoperative outcomes in older patients undergoing scheduled (non-emergency) surgery

[2] To describe delivery of geriatrician-led CGA services for older surgical patients within the UK NHS and examine how services are funded

[3] To describe the geriatrician perceived barriers to the development of CGA services for older surgical patients

[4] To describe multimorbidity, cognitive impairment and frailty in patients aged over 60 years undergoing emergency and elective aortic and lower limb arterial procedures

[5] To describe the association between cognitive impairment and frailty and postoperative outcomes (primarily length of hospital stay)

[6] To determine the clinical feasibility of assessing cognitive impairment and frailty using different tools and methods (Montreal Cognitive Assessment, MoCA, Edmonton Frailty Scale, EFS, Timed up and go, TUG, gait velocity)

[7] To examine whether preoperative CGA and optimisation reduces length of stay in older patients undergoing vascular surgery compared to standard preoperative assessment processes

[8] To describe the distress related to an episode of postoperative delirium in older surgical patients and their relatives using the distress thermometer

[9] To examine the association between degree of distress and features of delirium on the Delirium Rating Scale both on resolution of delirium and at 12 month follow up

[10] To examine the association between recall of delirium and features of delirium on the Delirium Rating Scale

Chapter 2 - CGA in the perioperative setting; the literature

2.0 Introduction

As outlined above CGA and optimisation is an established method for evaluating and managing older patients in various different clinical settings. It involves a multidomain, interdisciplinary assessment aiming to describe both known pathology and previously undiagnosed conditions together with an evaluation of functional, psychological and social status. This multidomain assessment prompts the formulation of a short and longer term investigation plan with feasible patient centred treatment goals, and a clinical management plan including directions on monitoring progress and making adjustments as necessary.

A systematic review and narrative synthesis of the literature was undertaken to examine whether preoperative CGA affects postoperative outcomes in older patients undergoing scheduled (non-emergency) surgery. The methods employed in this review will now be discussed before presenting the results in the form of the published paper in section 2.2.

2.1 Methods – systematic review and narrative synthesis

The Cochrane database, the Centre for Reviews and Dissemination (CRD) and all protocols on the International prospective register of systematic reviews (PROSPERO) were examined to ensure that this question had not previously been addressed. The research question was defined using the PICO framework which considers the following four components;

Population (the population under study which in this case was older people undergoing elective surgery)

Intervention (what is being done, which in this case was the application of preoperative Comprehensive Geriatric Assessment and optimisation)

Comparators (other main treatment options, which in this case was standard preoperative assessment)

Outcome (measures of how effective the interventions have been, which in this case referred to postoperative outcomes whether medical, surgical or functional).

Using this framework, the search strategy was defined and is presented in the results section 2.2. The search was conducted using MEDLINE, EMBASE and Web of Science from 1980 – 2013 (week 26) and limited to English language. The potential for inclusion bias was minimised by searching trial databases and grey literature. All identified abstracts were then screened according to the predefined inclusion and exclusion criteria presented below.

Inclusion criteria;

Experimental or quasi-experimental trials (randomised controlled trials, observational before-and-after studies, quality improvement programmes)

Studies that employed multidomain preoperative assessment regardless of whether this process was undertaken by a full multidisciplinary team or a single healthcare practitioner.

Exclusion criteria;

Case reports, case series, editorials

Studies where CGA was used purely as a risk assessment tool (without optimisation following the assessment)

Studies which only assessed patients using a single domain (e.g. frailty)

Studies where no postoperative outcomes were reported

Studies where the postoperative outcome was only delirium

Studies of enhanced recovery programmes as opposed to CGA

A second researcher (Jugdeep Dhesi, PhD supervisor) also independently screened all identified abstracts according to the following predefined inclusion and exclusion criteria. Discrepancies between the two reviewers were resolved by a third reviewer (Danielle Harari, PhD supervisor). Full text papers were obtained and assessed for risk of bias according to Cochrane guidelines in terms of selection; performance; detection; and attrition.

As anticipated from an existing knowledge of the available literature and an awareness of the type of studies used to evaluate complex multicomponent interventions, heterogeneity in the methods, study populations, and outcome measures made meta-analysis unfeasible. Therefore, as meta-analysis could not be used to statistically analyse heterogeneity in study results, the process of narrative synthesis was instead employed with an a priori decision to do so as recorded in the PROSPERO database before the work was undertaken. Narrative synthesis methodology was appropriate for this review as there was unlikely to be a large number of articles identified and both randomised and non-randomised studies were included. The process of narrative synthesis is emerging and the guidelines supporting this methodology are

consequently being adjusted in line with ongoing research. The narrative synthesis undertaken in this thesis was performed in accordance with the Cochrane Consumers and Communication Review Group (CCRG) guidelines, the framework presented by the University of York and the Guidance on the Conduct of Narrative Synthesis in Systematic Reviews [61-63].

Narrative synthesis

The following steps were undertaken;

Step 1 - all identified papers were first read and re-read several times with the key points recorded in order to ensure familiarity with the literature. In particular important similarities and differences in trial design, patient populations, the CGA intervention being studied and outcome measures were noted with a focus on exploring whether the heterogeneity in results could be attributed to different study designs.

Step 2 - all included studies were then grouped according to the design (randomised, non-randomised) and results tabulated.

Step 3 - data was translated using content analysis

Step 4 - relationships in the data were explored using grouping and textual descriptions

Step 5 - the robustness of the synthesis was evaluated and presented using critical reflection on the synthesis process.

Table 5 shows the specific tools used in the narrative synthesis.

Table 5. Tools used in narrative synthesis

Step in narrative synthesis	Tool or technique used
Developing a primary synthesis	Tabulation
Exploring relationships between studies	Textual descriptions Groupings or clusters
Assessing robustness of the synthesis product	Critical reflection on synthesis process including appraisal of quality of literature reviewed in narrative synthesis

Limitations

Clear limitations exist in a non-statistical approach to the analysis of heterogeneous study findings. However, the technique of narrative synthesis was selected as opposed to forcing meta-analysis of heterogeneous randomised and non-randomised study designs in a variety of different patient groups risking obscuration of understanding by attempting to homogenise findings. Application of an established framework for conducting such non-statistical data synthesis increased the translatability and robustness of the findings and set the scene for the remainder of the programme of work presented in this thesis. In addition, the application of English language filters to the search strategy may limit the generalisability of this work. This was necessary due to the time and resource constraints on this work as part of a PhD. However, the impact of any potential bias from limiting the search to articles written in English only is not thought to be significant as in other nations where English is less widely used as an academic language for publication, the speciality of geriatric medicine and

therefore the widespread use of CGA and optimisation either clinically or in the research setting is not commonplace. The findings of the systematic review and narrative synthesis are presented in the next section 2.2.

2.2 Results

Contribution of each co-author to publication

All authors of this paper provided substantial contributions to conception and design of the project. Judith Partridge designed and executed the systematic review with Jugdeep Dhesi and Danielle Harari performing the second independent abstract review and resolution of disputes respectively. Judith Partridge, Jugdeep Dhesi and Finbarr Martin analysed the data with additional interpretation from Danielle Harari. The article was drafted by Judith Partridge with revision and final approval from all co-authors.

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Review Article

The impact of pre-operative comprehensive geriatric assessment on postoperative outcomes in older patients undergoing scheduled surgery: a systematic review

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Summary

Comprehensive geriatric assessment is an established clinical approach. It reduces mortality and improves the physical wellbeing of older people in the community or hospitalised for medical reasons. Pre-operative comprehensive geriatric assessment seems a plausible method for reducing adverse postoperative outcomes. The objectives of this systematic review and narrative synthesis are to describe how pre-operative comprehensive geriatric assessment has been used in surgical patients and to examine the impact of comprehensive geriatric assessment on postoperative outcomes in older patients undergoing scheduled surgery. We searched MEDLINE, EMBASE and Web of Science from 1980 to 2013 (week 26). We included five studies: two randomised controlled trials and three before-and-after intervention quasi-experimental studies. Patient populations, interventions and outcome measures varied between studies. Both the randomised trials showed benefit on postoperative outcomes, including medical complications. Two of the before-and-after studies reported a positive impact on postoperative length of stay and other outcomes. The heterogeneity of study methods, populations, interventions and outcomes precluded meta-analysis. Based on this narrative synthesis, pre-operative comprehensive geriatric assessment is likely to have a positive impact on postoperative outcomes in older patients undergoing elective surgery, but further definitive research is required. Clinical services providing pre-operative comprehensive geriatric assessment for older surgical patients should be considered.

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An increasing proportion of the ageing population is undergoing surgery [1]. Despite the benefits of surgery seen in this population, the rate of adverse postoperative outcomes increases with age [2]. Postoperative complications are predominantly medical rather than surgical [3], and their increased rate is associated with physiological age [4], multimorbidity [5, 6] and geriatric syndromes, including frailty [7], sarcopenia [8] and delirium [9]. Although adverse postoperative outcomes and the risk factors for developing these are well described in older surgical patients [2], a national UK report has highlighted deficiencies in the care provided to this patient population [10]. Furthermore, pre-operative assessment has not been adapted to identify and modify these geriatric syndromes and multi-morbidity

proactively, with the aim of improving postoperative outcomes.

Comprehensive geriatric assessment (CGA) is an established method for evaluating and optimising physical, psychological, functional and social issues in older patients to improve longer-term outcomes. It involves a multi-domain assessment, which is usually interdisciplinary and is followed by the planning and implementation of investigations, treatment, rehabilitation and longer-term follow-up. Table 1 describes the components of CGA [11]. In medical inpatients [12] and community-dwelling older people [13], CGA has been shown to improve mortality at 36-month follow-up, increase the chance of living independently at home, and confer a positive effect on physical function.

A recent Cochrane meta-analysis of 22 trials of 10 315 hospitalised participants compared CGA with standard care [14]. The analysis was reported as odds ratios, but in terms of relative risk, CGA significantly increased the participants' relative risk (95% CI) of being both alive and in their own homes: at 6 months, 1.07 (1.03–1.12), $p = 0.0002$; and at a median of 12 months, 1.06 (1.02–1.10), $p = 0.003$. Furthermore, the relative risk of being institutionalised was less with CGA intervention, 0.83 (0.75–0.91), $p < 0.0001$ [14]. Thorough multi-domain assessment, followed by employment of comprehensive patient-centred plans, is thought to achieve the reductions in morbidity and mortality observed following CGA.

Table 1 Components of comprehensive geriatric assessment.

Domain	Items to be assessed
Medical	Co-morbid conditions and disease severity Medication review Nutritional status Problem list
Mental health	Cognition Mood and anxiety Fears
Functional capacity	Basic activities of daily living Gait and balance Activity/exercise status Instrumental activities of daily living
Social circumstances	Informal support from family or friends Social network such as visitors or daytime activities Eligibility for being offered care resources
Environment	Home comfort, facilities and safety Use or potential use of tele-health technology, etc. Transport facilities Accessibility to local resources

In contrast to the literature about medical inpatients, the use of CGA in surgical and cancer populations is often limited to the 'assessment' component of the process, which has been used for prognostication in several surgical and oncological studies [15]. This focus on assessment rather than optimisation reflects the limitations observed in standard pre-operative assessment processes. Given the increasing awareness of the challenges presented by the growing older surgical population, this systematic review aims to address the question 'does pre-operative CGA affect postoperative outcomes in older patients undergoing scheduled surgery?'

Methods

We searched MEDLINE, EMBASE and Web of Science databases from 1980 to 2013 (week 26; see Appendix for details). We examined identified references for all relevant full-text papers. The search was limited to English language articles only.

Two researchers (JP and JD) independently screened all identified abstracts according to the following pre-defined inclusion and exclusion criteria. Discrepancies were resolved through a third reviewer (DH).

We considered all experimental or quasi-experimental trial designs for inclusion (randomised controlled trials, observational before-and-after studies or quality improvement programmes), but we excluded case reports, case series and editorials. Studies where a multi-domain assessment was performed pre-operatively were included, regardless of whether this intervention was undertaken by a full multidisciplinary team or just a single healthcare professional, such as an internist, hospitalist or general physician. Trials were excluded if they employed CGA purely as a risk assessment tool for adverse postoperative outcomes. Similarly, studies were excluded if they assessed only one CGA domain, such as frailty, rather than employing a full multi-domain assessment and optimisation plan, or

Table 2 Tools and techniques used to complete each element of the synthesis process.

Element or step in synthesis process	Tool or technique used
Developing a theory	
Developing a primary synthesis	Tabulation Textual descriptions Groupings or clusters
Exploring relationships within and between studies	Qualitative case reports /textual descriptions
Assessing the robustness of the synthesis product	Reflecting critically on the synthesis process

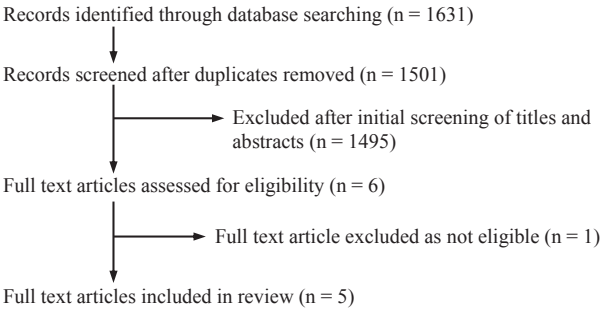

Figure 1 Included and excluded studies.

when there were no outcomes, or the outcome was restricted to delirium. We also excluded studies of enhanced recovery programmes. Inclusion bias was limited by searching trial databases and grey literature.

Full-text articles were assessed for risk of bias in the following domains, according to Cochrane guidelines: selection; performance; detection; and attrition. We conducted a narrative synthesis when meta-analysis was not possible, in accordance with guidance from a methodology review [16], using tools and techniques shown in Table 2.

Results

The electronic searches identified 1501 potentially relevant publications (Fig. 1). Six full-text articles were eligible following screening of abstracts [17–22]. One study was excluded after review of the full-text article [19] as no CGA-based intervention was undertaken. We included two randomised controlled trials [20, 21] and three before-and-after studies [17, 18, 22]. Heterogeneity in study design, population, intervention and outcomes precluded meta-analysis. Table 3 summarises the included studies.

Randomised controlled trials

Both randomised controlled trials identified were conducted in the USA, and used a pre-operative 'hospitalist' or internal medicine assessment as the intervention. One trial examined patients aged over 50 years undergoing various types of elective non-cardiac surgery (ENT, orthopaedics, ophthalmology, gastrointestinal, urological, plastic, neurosurgery, vascular, dental) [21]. The other study included all patients over the age of 18 years undergoing elective orthopaedic procedures: despite the inclusion of younger patients, the mean (SD) ages in the intervention and control groups were 72.6 (10.6) and 73.7 (8.7) years, respectively [20]. Outcome measures included length of stay, cancellations, resource use and postoperative medical complications.

Macpherson et al. [21] recruited 355 participants older than 50 years with life expectancies more than 30 days. Following pre-operative referral by surgical teams, participants were randomly allocated to intervention or control, stratified by surgical procedure. The intervention was a pre-operative outpatient internal medicine assessment, the results of which were delivered to the surgical ward on the day of hospital admission. In this 1994 study, the control group did not receive any pre-operative assessment before hospital admission and internal medicine consult was sought only at the discretion of the surgeon. Total and postoperative lengths of stay were not significantly different between the two groups. Pre-operative length of stay was reduced in the intervention group by 1.3 (0.8–1.8) days, from 2.9 to 1.6 days, $p < 0.001$. Cancellations after admission were reduced from 22 to 10 ($p = 0.03$) in the intervention group. Total resource usage was unchanged between the groups, but a greater proportion of resources were used in the outpatient setting in the intervention group. The opportunity costs of cancellations were not included in the economic analysis.

Huddleston et al. [20] enrolled 526 patients aged 18 or more years when scheduled for elective primary, or revision, total knee or hip arthroplasty. Allocation was stratified according to surgical procedure. The

Table 3 Summary of included studies.

Author/Year/Region	Patient population	Intervention	Comparison	Outcome measures	n	Summary of findings	Issues with study
Before-and-after studies							
Ellis 2012 [22] Airdrie, UK	Aged 65 Elective orthopaedic, urological, gastrointestinal surgery	Nurse/OT with expertise in geriatric medicine used MMSE, Barthel and referred and managed identified conditions using protocols (already in use in the geriatric medicine service)	Usual nurse-led pre-operative assessment	Length of stay MMSE Delay to surgery Cancellations Postoperative infection	313 (141 pre, 172 post)	Reduction in cancellations and delays to surgery 45% reduction in length of stay	Underpowered Redesign of process change during study period increasing potential for period effect Unblinded researchers
Harari 2007 [18] London, UK	Aged 65+ Elective orthopaedic surgery	Pre-operative multidisciplinary CGA and optimisation	Usual nurse-led pre-operative assessment (with referral to anaesthetists /physicians as required)	Length of stay Medical complications	108 (54 pre-POPS, 54 POPS)	31% reduction in median length of stay Reduction in medical complications (pneumonia, delirium, pressure sores, inadequate pain control, delayed mobilisation, unnecessary urinary catheter)	Potential for period effect Unblinded researchers
Richter 2005 [17] Alabama/ New York, USA	Aged 60+ Elective pelvic floor surgery	'Enhanced pre-operative assessment' of ADL, IADL, TUAG, clock drawing, nutritional assessment, GDS, social support scale	Usual pre-operative evaluation by physicians	Change in scores on physical and mental components of SF36	62 (32 in enhanced assessment arm, 30 in routine arm)	No change in outcomes measure (SF36 scores) following 'enhanced assessment'	No optimisation Insensitive outcome measure Potential for period effect Unblinded researchers

Table 3 (*Continued*)

Author/Year/Region	Patient population	Intervention	Comparison	Outcome measures	n	Summary of findings	Issues with study
Randomised, controlled trials							
MacPherson 1994 [21] Pennsylvania, USA	Age 50+ Elective surgical patients referred for internist review pre-operatively	Internal medicine assessment 3 weeks before surgery Laboratory and radiology tests	Admission to hospital without pre-operative assessment Patients were also seen by an internist if referred during admission by surgeons	LOS Admissions who did not then undergo surgery Resource use (laboratory, radiology, consultations)	355 (176 intervention group, 179 control group)	Reduction in admissions who did not undergo surgery No reduction in LOS or resource usage	Bias Not CGA Good stratification of randomisation
Huddleston 2004 [20] Rochester, USA	Aged 18+ (mean age 73 years) Elective orthopaedics	Collaborative hands on hospitalist input pre- and postoperatively	Internist ± anaesthetic pre-operative assessment Orthopaedic care postoperatively	Medical complication rate Length of stay	526 (251 intervention, 254 control, 21 excluded)	Reduced complications in intervention group No difference between LOS if 'adjusted for discharge delays' LOS shorter in intervention group Cost neutral	No blinding

ADL, activities of daily living; CGA, complete geriatric assessment; GDS, geriatric depression scale; IADL, instrumental activities of daily living; LOS, length of stay; MMSE, mini-mental state examination; OT, occupational therapy; POPS, proactive care of older people going to have surgery; TUAG, timed up and go.

control group received standard pre-operative laboratory investigation, physiotherapy and nursing education, according to an established clinical pathway. Postoperatively, the orthopaedic team were responsible for daily care, and were the gatekeepers for referrals to other services and specialities. Participants in the intervention group received collaborative hospitalist/orthopaedic care. Pre-operatively, patients were assessed by the hospitalists, who took a lead in postoperative care. Comprehensive geriatric assessment significantly reduced postoperative complications by 11.8 (2.8–20.7)%, from 50.2 to 38.4%, $p = 0.01$, and the time to be 'fit for discharge' by 0.5 (0.8–0.1) days, from 5.6 to 5.1 days, $p < 0.001$. Total costs were unchanged, $p > 0.2$.

Before-and-after intervention quasi-experimental studies

All three before-and-after intervention studies compared outcomes after pre-operative assessment based on the principles of CGA with historical standard care, administered either by physicians or nurses, depending on the routine practice within the centre. One study was conducted in the USA [17] and the other two in the UK [18, 22]. Outcome measures were comparable to the randomised controlled trials, including length of stay, delay to surgery and cancellations, quality of life and postoperative medical complications such as infections, delirium and delayed mobilisation. The surgical populations studied were all aged over 60, and all underwent elective orthopaedic, urological, gastrointestinal or gynaecological procedures.

Ellis et al. recruited patients aged over 65 years scheduled for orthopaedic, urological or gastrointestinal surgery [22]. An additional inclusion criterion was one or more difficulties with: cognition; mobility; falls; daily activities; or home circumstances. In the control phase of the study, 141 patients underwent routine evaluation by a pre-operative assessment clinic nurse, and were then seen by a care of the elderly nurse who recorded baseline data on medical issues, cognition, falls, nutrition, functional ability, continence and carer roles. The need for onward referrals was recorded by the care of the elderly nurse, but no referral was actually made. One hundred and seventy-two patients were recruited in the intervention phase, where a care of the elderly nurse and an occupational therapist made relevant referrals to physiotherapy, occupational therapy, dietetics, social work, the falls team, general practice, a district nurse and other support agencies. Fewer operations were cancelled during the intervention phase, 17.7% vs. 5.2%, $p < 0.001$. The mean (SD) inpatient stay fell from 8.9 (7.6) to 4.9 (5.0) days, $p < 0.001$. Postoperative complications were reduced from 8.5% to 2.3%, $p = 0.01$.

Harari et al. enrolled 108 elective orthopaedic patients aged over 65 [18]. The initial modelling phase involved screening patients aged over 65 years on elective orthopaedic waiting lists using a self-completion questionnaire identifying co-morbidities, functional limitations and social support. This identified unmet needs that could adversely impact on postoperative outcomes. Based on this modelling, a geriatrician-led multidisciplinary team was established. The proactive care of older people undergoing surgery (POPS) team consisted of a consultant geriatrician, clinical nurse specialist, occupational therapist, physiotherapist and social worker and undertook CGA pre-operatively within the outpatient setting. Fifty-four patients in the pre-POPS cohort received standard pre-operative assessment by a pre-operative assessment clinic nurse. The POPS group had fewer medical complications and other unwanted occurrences: pneumonia 20% vs 4%, $p = 0.008$; delirium 19% vs 6%, $p = 0.036$; pressure sores 19% vs 4%, $p = 0.028$; inadequate analgesia 30% vs 2%, $p < 0.0001$; delay to mobilisation 28% vs 9%, $p = 0.012$; and inappropriate catheter use 20% vs 7%, $p = 0.046$. The mean (SD) length of stay was reduced from 15.8 (13.2) days to 11.5 (5.2) days, $p = 0.028$, with fewer delays relating to medical complications or waits for domiciliary occupational therapy equipment.

Richter et al. recruited a convenience sample of 62 patients aged over 60 scheduled for pelvic floor surgery [17]. During the 6-month control phase of the study, 30 patients received standard pre-operative physician evaluation. In the intervention phase, 32 patients received additional pre-operative assessment of function (Activities of Daily Living/Instrumental Activities of Daily Living), mobility (Timed up and go), cognition (clock drawing), nutrition (Mini Nutritional Assessment), mood (Geriatric Depression Scale) and

social support (Social Support Scale). Research nurses recorded the results in the medical records, which then informed postoperative care delivered by surgical teams and resident physicians. Both groups completed the same two outcome measures, pre-operatively, at 6 weeks and at 6 months postoperatively: the Short Form 36 (SF 36), a generic multi-domain quality of life assessment tool; and a Utility Item Score, a subjective score of how well they felt, between 0 (dead) and 100 (full health). The study was powered to detect a difference between groups of 10 points on the SF 36 score, calculated as the change from pre-operative to post-operative scores, at both 6 weeks and 6 months. There were no significant differences in these scores between the two groups. Notably, the authors concluded that the majority of the study participants were in good health, with no functional limitation, no mood disorder and good social support networks.

Discussion

Five full-text articles were included in this narrative synthesis review. Meta-analysis was precluded by the heterogeneity of the surgical patient population, the CGA intervention and the differing outcome measures used. Although there are clear limitations in these studies as discussed below, narrative synthesis suggests that pre-operative CGA may be beneficial in reducing adverse postoperative outcomes, in terms of both patient-specific clinical measures and process measures.

Numerous study abstracts were identified in which CGA was used to predict the risk of adverse post-operative outcomes in both surgical and oncology patients. However, the majority focused on the assessment component of CGA without introducing specific management plans aimed at optimising modifiable risk factors for adverse postoperative outcomes. Published evidence in medical patients concludes that *both* assessment *and* patient-specific optimisation are required in order for CGA intervention to be successful [12–14]. For this reason, those abstracts that only used the assessment component of CGA, without modification, were excluded from this synthesis. Five studies remained eligible for review.

Conducting research into the impact of multi-component interventions is fraught with difficulties; however, the Medical Research Council (MRC) does provide a clear framework for such research [23]. Despite the availability of these guidelines since 2000, there were clear limitations in the studies presented in this review including standardisation of the design and delivery of the interventions, incorporation of factors specific to the local context, and the inability to blind researchers as contemporaneous caregivers (a source of observer bias in both the randomised controlled trials and pre- and post-intervention cohort studies).

The main limitations of the two RCTs relate to whether the intervention constituted CGA. Macpherson et al.'s study [21] was well powered with stratified randomisation according to surgical procedure, but the methods did not state clearly how patients were assessed or optimised. Instead, it focused on resource use, namely laboratory and radiology tests ordered and the setting in which these investigations were arranged. This limits the study's relevance to the review question posed in this study. Similarly, Huddleston et al. [20] used proxy CGA delivered by a non-geriatrician internist both pre- and postoperatively. Although the intervention was effective in terms of a reduction in postoperative complications, it is difficult to state conclusively that this was due to CGA per se rather than the involvement of any physician in the care of surgical patients. Length of stay was shorter in the intervention group, but only when adjusted for organisational discharge delays. This suggests that although postoperative medical complications were less common, functional or social issues may not have been identified pre-operatively or addressed in a timely fashion until the end of the hospitalisation, when the patients were 'medically fit for discharge' but still required extra care, rehabilitation or institutional placement.

The before-and-after studies have additional methodological shortfalls. The period effect between assessments may introduce bias resulting from confounding factors unrelated to the intervention being tested, such as organisational change, alterations to clinical practice or staff variation. Attempts to minimise the period effect were made by the studies included in the review using a short study timeframe [18]. The effect of organisational change (the introduction of a centralised appointment system), although acknowledged in one study [22], may still have biased results. The inability to blind researchers was also acknowledged and attempts to reduce sub-

jective observer bias were made (although not eliminated) using objective endpoints such as length of stay and postoperative complications [18, 22].

The two before-and-after studies that demonstrated a reduction in postoperative complications and total length of stay employed both components of CGA – assessment and optimisation with follow-through delivery of care [18, 22]. In contrast, Richter et al. used several well-validated assessment tools, but failed to perform any optimisation or establish management plans for the issues identified during the pre-operative assessment process. The results of the scores were documented for potential action by the usual care teams, but this does not constitute full CGA and the lack of impact from CGA seen in this study may be because no meaningful 'hands on' optimisation or 'follow through' occurred. The primary outcome measure, a change in several components of the SF 36, may not be a sensitive enough tool to identify change over a short time period and therefore the lack of impact from CGA in this study may simply reflect use of an insensitive outcome measure.

In summary, this systematic examination and narrative synthesis of the literature suggests that pre-operative CGA may have a positive impact on postoperative outcomes (medical complications and length of stay) in older patients undergoing elective surgery. However, the current evidence is inconclusive and definitive research evaluating pre-operative CGA is required. Such research should be conducted according to the MRC guidelines [23], using an adequately powered, randomised, controlled design and outcome measures relevant to all stakeholders, including patient-related and -reported outcomes, process measures and economic evaluation. Such studies are likely to require the use of cluster randomisation methods. The studies should employ CGA intervention in its entirety (assessment and optimisation), and focus on the determination of which particular component of the intervention has the most impact on outcome measures, so as to investigate the so-called 'black box' effect of complex interventions.

Although the results of this narrative synthesis are not conclusive, a pragmatic interpretation of the available literature is necessary. Clinicians should consider establishing collaborative services for older surgical patients with a patient-centred pathway at the core. This may require multidisciplinary input from surgeons, anaesthetists, geriatricians, organ-specific physicians, therapists, nurses and patients as well as local managers and commissioning groups. Resources to facilitate this include the American College Surgeons National Surgical Quality Improvement Programme (ACS NSQIP®)/American Geriatrics Society Best Practice Guidelines *Optimal Preoperative Assessment of the Geriatric Surgical Patient* [24], the British Geriatrics Society Best Practice Guide *Perioperative care for older patients undergoing surgery* [25] and the Association of Anaesthetists of Great Britain and Ireland guidelines *Peri-operative care of the elderly* presented in this supplement [26].

Competing interests

No external funding or competing interests declared.

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Appendix

Search strategy used

1. (exp Geriatric Assessment/), 2. (cga.mp. [mp = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]), 3. ((comprehensive adj2 geriatric assessment).mp), 4. (multicomponent intervention*.mp), 5. (multi-component intervention*.mp), 6. (exp Patient Care Team/), 7. (liaison.mp.), 8. (collaborat*.mp.), 9. (multidisciplinary.mp.), 10. (multi-disciplinary.mp.), 11. (exp Aging/), 12. (exp Aged/or exp "Aged, 80 and over"/), 13. (exp Geriatrics/), 14. (geriatr*.mp.), 15. (ag?ing.mp.), 16. (exp Specialties, Surgical/), 17. (Surgical Procedures, Elective/),18. (exp Surgical Procedures, Operative/), 19. (surg*.mp), 20. (exp Perioperative Care/), 21. (exp Perioperative Period/), 22. (peri-operative.mp.), 23. (perioperative.mp.), 24. (Preoperative Care/), 25. (pre-operative.mp.), 26. (preoperative.mp.), 27. (postoperative.mp.), 28. (post-operative.mp.), 29. (elective.mp.), 30. ((planned adj10 surg*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]), 31. (1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10), 32. (11 or 12 or 13 or 14 or 15), 33. (16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28), 34. (29 or 30), 35. (31 and 32 and 33 and 34), 36. (limit 35 to english language).

2.3 Conclusions

This systematic review and narrative synthesis suggests that employing CGA methodology, with its established evidence base in medical and community dwelling older people, in the preoperative setting may be effective in improving adverse postoperative outcomes but to date this is not conclusive. Furthermore, the extent to which CGA and optimisation based geriatric medicine services for older surgical patients already exist in the UK is unknown.

Chapter 3 - CGA in the perioperative setting; the national picture in the UK

3.0 Introduction

So far in this thesis it has been shown that older patients suffer a preponderance of adverse postoperative outcomes due to the risk profile conferred by multimorbidity and geriatric syndromes such as frailty and cognitive issues including delirium. A potential evidence based methodology to mitigate this risk profile exists in the form of CGA and optimisation. Whilst a robust evidence base for the benefit of CGA exists in the medical, community and hip fracture setting the systematic review and narrative synthesis presented in chapter 2 suggests that more research is required to definitively demonstrate the role that preoperative CGA may have in improving outcomes in the perioperative setting. The MRC framework for developing and evaluating complex interventions requires a phase of modelling process and outcomes. The next step in this phase, was to examine the current provision of geriatrician led CGA and optimisation based services for older surgical patients in NHS hospitals in the UK. This component of the research programme was particularly topical as the national reports advocating the involvement of geriatricians in the perioperative pathway had been published in the two to three years preceding this and the extent to which the recommendations from these reports had been translated into routine clinical practice was not yet known. Furthermore, when considered in the overall scheme of work for this thesis, and based on the MRC guidance, ensuring sustainability of any future CGA intervention was paramount and therefore an understanding of the current barriers to service development was required. A national survey was therefore undertaken to describe;

- the delivery of geriatrician-led CGA services for older surgical patients within the UK NHS and examine how services are funded
- the geriatrician perceived barriers to the development of CGA services for older surgical patients

3.1 Methods - survey

An electronically delivered, anonymously completed, national survey of geriatric-medicine clinical leads in UK acute hospital trusts was undertaken. On discussion with the NHS trust research and development department no ethical approval was required for this study.

Developing the survey tool

A survey tool addressing the research objectives above was designed, piloted, refined and externally validated. The tool was divided into three main sections; preoperative care, postoperative care and organisational information. The content of these sections was derived from themes identified in published reports identified through the literature review. Questions used a combination of multiple choice, ranking and Likert formats and were piloted for readability, non-ambiguity, survey length and content validity by a convenience sample of consultant geriatricians working at Guys and St Thomas' and local centres. Following the pilot phase, the survey tool was refined and sent to ten expert clinicians experienced in the perioperative medicine for older people in order to ascertain external validity. This expert panel were identified through a Perioperative medicine for Older People undergoing Surgery (POPS) specialist interest group whose details are held at the British Geriatrics Society (BGS). The overall

content validity ratio was 0.66 which was above the validity threshold of 0.62 for ten expert raters. Content validity refers to the extent to which a measure, or in this case the survey tool, represents all aspects being evaluated. For example if the survey tool accurately assessed geriatrician-led CGA services but neglected to examine the barriers to establishing such services, the tool would lack content validity in terms of the predefined premise of the study. In this study the assessment of content validity of the survey tool was evaluated using Lawshe's method where an expert panel is used to achieve agreement regarding how essential each survey question is [64]. The survey tool can be seen in appendix 4.

Identifying a sample and ensuring an adequate response rate

Ensuring a representative sample of participants and achieving a high response rate was key to minimising bias in this survey. To this end the survey was undertaken under the auspices of the BGS which is the national professional body for geriatricians in the UK. The BGS hold a list of email addresses for clinical leads in geriatric medicine at all UK acute NHS trusts where older people undergo surgical procedures and this list constituted the study sample. The invitation email sent to all geriatricians on this BGS list was sent jointly from the PhD student, supervisors (Jugdeep Dhesi, Danielle Harari, Finbarr Martin) and the BGS with the aim of improving the response rate by endorsement of the work by the national society. An electronic survey format using Survey Monkey software was chosen due to the geographical area being sampled and the ease of analysis using this package.

Invitation emails were sent to all potential participants with a weblink to the survey.

Non-respondents were contacted again at two, four and six weeks with a further invitation to participate thus maximising the response rate obtained.

Analysing the data

Completed surveys were electronically exported from survey monkey into SPSS version 21 where responses were analysed using descriptive statistics and reported by themes.

Limitations

The limitations of using this methodology are those inherent in all surveys. There is the potential issue of response bias with those trusts providing perioperative services for older patients more likely to participate. However, the survey showed only very few perioperative medicine services in existence across the UK suggesting that this potential bias was likely negated by the high response rate seen. With an anonymous survey the potential for ambiguity in the interpretation of questions exists but the rigorous process of piloting and refining the survey tool aimed to mitigate this issue.

3.2 Results

Contribution of each co-author to publication

All authors of this paper made substantial contributions to conception and design of the study. Judith Partridge with supervision from Jugdeep Dhesi designed the sampling frame, approaches to maximising response rate and survey tool. Intellectual refinement provided by Adam Gordon, Danielle Harari and Finbarr Martin. Data acquired by Judith Partridge, Geraint Collingridge and Jugdeep Dhesi and analysed by Judith Partridge with supervision from Jugdeep Dhesi. Manuscript drafted by Judith

Partridge and Jugdeep Dhesi with revision by Danielle Harari, Adam Gordon and Finbarr Martin.

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Where are we in perioperative medicine for older surgical patients? A UK survey of geriatric medicine delivered services in surgery

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Abstract

Introduction: national reports have highlighted deficiencies in care provided to older surgical patients and suggested a role for innovative, collaborative, inter-specialty models of care. The extent of geriatrician-led perioperative services in the UK (excluding orthogeriatric services) has not previously been described. This survey describes current services and explores barriers to further development.
Methods: an electronic survey was sent to clinical leads for geriatric medicine at all 161 acute NHS health care trusts in the UK. Reminders were sent on three occasions over an 8-week period. The survey examined preoperative and postoperative care and organisational issues. Responses were analysed descriptively.
Results: there were 130 respondents (80.7%). One-third (38) of respondents described providing some geriatric medicine input in older surgical patients. Preoperative services existed in 15 (12%), where 14 provided risk assessment and 13 preoperative optimisation. Twenty-six respondents (20%) delivered care postoperatively, of them 10 took a reactive approach, 11 a proactive approach and 5 provided a combination of reactive and proactive care. Barriers to establishing perioperative geriatric medicine services included funding, workforce issues and a lack of inter-specialty collaboration.
Conclusion: a national appetite exists to provide geriatrician-led services to older surgical patients yet the majority of existing services remain reactive and do not use comprehensive geriatric assessment as an organising principle. This survey suggests that funding for geriatricians in perioperative care has not yet been universally established. Future efforts should focus on dissemination of experiential knowledge and published resources, collaboration with commissioners and empirical research to overcome the barriers described.

Keywords: *older adults, perioperative medicine, liaison geriatrics, health services, clinical pathways*

Introduction

Despite recent advances in surgical and anaesthetic techniques, older people undergoing both elective and emergency surgery continue to experience excess adverse postoperative outcomes compared with younger patients [1]. Adverse outcomes have been attributed to age-related physiological change, multimorbidity [2] and the prevalence of geriatric syndromes [3, 4]. There has been recent focus on establishing effective clinical pathways to ensure that evidence-based methods are used to risk assess and optimise patients perioperatively, with UK national reports recommending routine daily input from geriatric medicine teams for older patients undergoing surgery [5]. It has been recognised that the contribution of geriatricians is likely to involve evaluation and management of risk, promoting shared decision-making and co-ordinating the inputs of a multidisciplinary team [6].

Outside the surgical context, geriatricians have improved patient-related outcomes by undertaking comprehensive geriatric assessment (CGA), defined as a multidimensional interdisciplinary diagnostic process focused on determining a frail elderly person's medical, psychological and functional capability to develop a coordinated and integrated plan for treatment and long-term follow-up [7]. CGA has a strong evidence base in acute hospital [8] and community care settings [9]. If geriatricians are to improve outcomes in older surgical patients, it is likely that this will also be through CGA [10].

To enable future service development and research about perioperative geriatric medicine, this survey aimed to establish

(i) Whether geriatrician-led services exist for older surgical patients within the UK?
(ii) What geriatrician-led perioperative services consist of and how they are funded?
(iii) What geriatricians perceive as the barriers to the future development of such services?

Methods

The survey (Supplementary data are available in *Age and Ageing* online, Appendix 1) consisted of 18 questions, divided into three main sections; preoperative care, postoperative care and organisational information. The survey content was based on themes identified through national reports and best practice guidelines [5, 6, 11–14]. Questions used a combination of multiple choice, ranking and Likert formats. The survey was reviewed for readability, non-ambiguity and content validity by 10 expert clinicians experienced in the perioperative management of older people. The overall content validity ratio was 0.66, above the validity threshold of 0.62 for 10 expert raters [15].

Participants were identified through a comprehensive list of clinical leads for geriatric medicine at all UK trusts held by the British Geriatrics Society. All were sent an email with a weblink to an electronic version of the survey. Non-respondents were contacted again at 2, 4 and 6 weeks with a further invitation to participate. Responses were analysed using basic descriptive statistics and reported by themes.

Results

Provision of geriatric medicine clinical care for surgical patients

Responses were received from 130 of 161 trusts undertaking emergency and elective surgery, a response rate of 80.7%. Thirty-eight respondents (29.2%) provided geriatric medicine input into the care of older surgical patients. The variety in clinical services provided by geriatricians to the older surgical population is represented in Figure 1.

Of the 38 trusts providing a service, 15 did so preoperatively, with focus on risk assessment in 14 trusts and medical optimisation in 13. Twelve trusts described CGA as the principle guiding preoperative assessment.

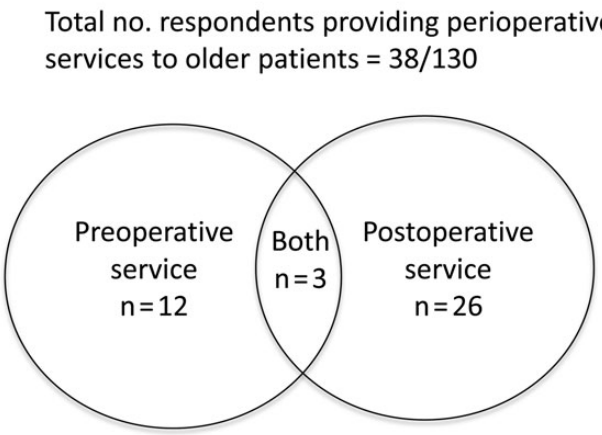
Of those trusts focussing on risk assessment, six used tools quantifying frailty and eight used anaesthetic perioperative risk-assessment tools as a routine part of preoperative assessment (American Society of Anaesthesiologists Score [16] in seven and physiological and operative severity score for the enumeration of mortality and morbidity (POSSUM) score [17] in one trust).

Of those trusts focussing on preoperative optimisation, nine used a geriatrician-led multidisciplinary team (MDT), whereas four used a geriatrician without an MDT.

Twenty-six trusts (68.4%) provided postoperative geriatric medicine input. This was provided following elective procedures in 14 and emergency surgery in 24. Ten trusts used 'reactive' models of care, where geriatricians attended following referrals from the surgical team, while 11 provided 'proactive' models, incorporating some component of active case-finding by geriatricians. A combined approach was taken in five trusts. When asked to reflect on the last surgical patient who they saw, geriatricians reported providing a variety of services (Table 1).

Method of risk assessment	n
CGA	12
Comorbities	8
Frailty	6
ASA	7
POSSUM	1
No risk assessment	1

Optimisation by	n
Geriatrician	4
Geriatrician led MDT	9



Model of care	n
Reactive	10
Proactive	11
Combined	5

Figure 1. Features of perioperative services provided by geriatric medicine in the UK.

Collaboration with other perioperative specialties

Only 20 respondents had spoken at surgical and 7 at anaesthetic audit meetings within their trust in the past year. For those who had presented, 20 respondents had presented once, 6 had presented twice and a single respondent three or more times. Twenty-two trusts had involved geriatricians in writing local clinical guidelines for older surgical patients. In the majority of cases, these covered delirium.

Organisational factors and perceived barriers to development of services

Fifty-four trusts did not provide dedicated funding to deliver geriatric medicine services to older surgical patients. A further 22 provided perioperative geriatric medicine input from within the operating budgets of geriatric medicine departments. For those trusts with ring-fenced funding for perioperative geriatrics, 13 provided this from the medical directorate, 5 from combined medical and surgical budgets and 9 from surgical directorates.

Where ring-fenced funding existed, this was predominantly used for consultant sessions (27 respondents), with eight trusts funding specialist registrar sessions and seven funding junior medical staff. Allied health professionals (AHPs) were also funded (clinical nurse specialist 10, physiotherapy 11, occupational therapy 13, and social worker 8). In some hospitals, AHP support was provided by extending the roles of existing falls, Parkinson's disease and Older Persons Liaison clinical specialists [18].

Barriers to the development of perioperative services for older surgical patients were explored by asking respondents to rank the importance of potential resources in expanding their services, with responses summarised in Figure 2.

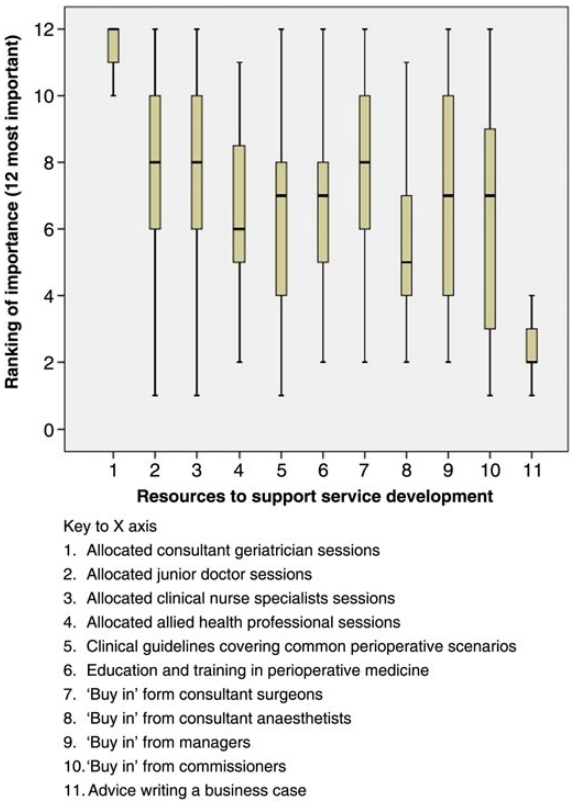


Figure 2. Respondents' views on what would help them to further develop perioperative services for older surgical patients.

Discussion

This is the first UK-wide survey examining the role of geriatricians in perioperative services for older surgical patients and shows that about a third of respondents offer such services. Only a small proportion of them explicitly recognise CGA as a guiding principle, despite the compelling evidence from other settings that the use of CGA improves clinical outcomes. The majority of respondents provided only postoperative services, did so reactively and focussed on emergency cases. This is contrary to emerging evidence that early proactive multidisciplinary CGA and optimisation can improve postoperative outcomes in older patients [10] and the weight of evidence from orthogeriatrics, suggesting that proactive services deliver better outcomes [19].

In the majority of trusts, geriatricians were not fully engaged as members of the perioperative team, with limited involvement in surgical and anaesthetic meetings and in the development of guidelines relevant to older surgical patients.

It is noteworthy that the majority of respondents cited funding difficulties as a barrier to establishing perioperative geriatric medicine services. The fact that only a minority received funding from surgical directorates suggests that the case for geriatricians and CGA may not be widely accepted outside our specialty.

The difficulty in recruiting geriatricians into perioperative medicine consultant posts reflects the mismatch between the demand for geriatricians and the number of specialists emerging from training. One way of bridging this gap would be to employ more nurse specialists to provide perioperative services for older people, yet this survey identified only 10 such posts across the UK.

The limitations of this study are those inherent in all surveys. There was the possibility of response bias; trusts with surgical liaison services may have been more likely to respond, resulting in over-representation. Potential ambiguity in interpretation of questions and therefore in response exists and it was not possible to interrogate responses in greater detail from an anonymous survey. However, the response rate was high for an online questionnaire [20], and the work

Table 1. Components of perioperative services for older surgical patients

Clinical service provided	No respondents
Postoperative medical management	18
Rehabilitation and goal setting	18
Discharge planning	15
Setting ceilings of care	13
Sanctioning move to geriatric medicine bed	11
Preoperative medical management	10
Sanctioning move to community rehabilitation facility	8
Assessment of capacity	7

we undertook to establish face and content validity went some way to addressing these concerns.

In conclusion, this survey demonstrates that the involvement of geriatricians in perioperative care of older people in the UK remains limited. Most services are reactive and oligodisciplinary, despite evidence from other settings that geriatricians are most effective when their care is proactive and delivered as part of a multidisciplinary team.

The difficulty in establishing funding suggests that the case for CGA in perioperative care may not be widely accepted outside our specialty. This may be addressed by dissemination of current good practice guidance [12–14, 21] and by addressing the paucity of empirical evidence regarding the effectiveness and translation of CGA into clinical pathways for older surgical patients.

Key points

- Adverse postoperative outcomes in older surgical patients can be due to inadequate management of perioperative risks.
- Surgeons, anaesthetists and geriatricians should work collaboratively to develop pathways of care for older surgical patients.
- This survey demonstrates enthusiasm from UK geriatricians to develop and lead such innovative services.
- Despite this fewer than a third of UK geriatric medicine departments provide such a service.
- Using published resources, research and collaboration with commissioners may overcome existing funding and workforce barriers.

Supplementary data

Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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3.3 Conclusions

In conclusion, from the findings presented in chapter 3, it is observed that , fewer than a third of UK NHS trusts currently provide geriatrician-led perioperative medicine services for older people. Furthermore, in the centres where services do exist these are predominantly postoperative and rarely incorporate preoperative CGA and optimisation. Funding and workforce are most commonly cited as the barriers to further service development.

The next chapter builds on this first step of the MRC framework to model process and outcomes, by using an observational study co-designed using patient and public involvement. This process helped to define the clinical issues and establish research outcomes measures that were important to patients and their families as well as relevant to clinicians and managers.

Chapter 4 – Developing a complex intervention; observational phase

4.0 Introduction

This chapter describes the development and results of an observational study which builds on work undertaken in the theoretical and modelling phases of the MRC framework presented in chapters 2 and 3. The observational study was undertaken to address the following objectives and in turn, to inform the development of the multicomponent intervention to be evaluated in the penultimate phase of the MRC research framework (chapter 5).

Study objectives;

- To describe multimorbidity, cognitive impairment and frailty in patients aged over 60 years undergoing emergency and elective aortic and lower limb arterial procedures
- To describe the association between cognitive impairment and frailty and postoperative outcomes (primarily length of hospital stay)
- To determine the clinical feasibility of assessing cognitive impairment and frailty using different tools and methods (Montreal Cognitive Assessment, MoCA, Edmonton Frailty Scale, EFS, Timed up and go, TUG, gait velocity)

4.1 Methods - observational study

Ethics

Ethical approval for this study was granted (11/H1102/010).

Setting

The study was undertaken at a large inner city teaching hospital with a tertiary referral practice for vascular surgery.

Subjects

Inclusion criteria

- Aged over 60 years
- Undergoing aortic aneurysm surgery or lower limb arterial procedures

Exclusion criteria

- Patients receiving palliative care for a terminal condition
- Patients admitted and discharged over the weekend (pragmatically chosen due the capacity of the researcher to capture these potential participants)
- Patients who were too unwell to complete the preoperative assessments tools or those with delirium

Recruitment and consent

Potential participants meeting the inclusion and exclusion criteria were approached on the vascular inpatient ward by the research fellow within 48 hours of their admission. At this initial meeting a patient information sheet was provided and explained and the project was outlined. Questions were answered and according to the ethical approval received, those patients who wished to participate provided written consent at that point. The patient information sheets, patient consent forms, consultee information sheets and consultee assent forms can be seen in appendices 5 - 8. According to

sections 30-34 of the Mental Capacity Act (2005) ethical approval was sought and granted to recruit patient participants who lacked capacity to consent. In these cases, a consultee was approached and asked to provide written assent on behalf of the participant. This approach was taken in order that bias, due to exclusion of those with cognitive impairment or dementia resulting in a lack of capacity to consent to study participation, was minimised.

Preoperative data collection

Baseline demographic data, comorbidities and medication history was obtained through a combination of patient interview and notes review. In particular, any patient-reported or collateral history of cognitive issues was noted and the medical record reviewed for prior mention of cognitive impairment or diagnosis of dementia. Cognitive status was examined using the Mini Mental State Examination (MMSE) which was in routine clinical use at the time, and the Montreal Cognitive Assessment (MoCA). The MoCA was chosen as it is a brief cognitive assessment tool with face validity for use in the often time-pressured preoperative period but has additionally been well validated in different patient populations with particular utility in comparison with the MMSE, in evaluating the executive dysfunction commonly observed in those with vascular cognitive impairment or vascular dementia [65]. Given the high proportion of older vascular surgical patients with vascular risk factors it was anticipated that the MoCA may be more useful than the MMSE in this patient group [66]. Given the constraints of an acute surgical ward all attempts were made to perform the MoCA in a calm, quiet environment without interruption.

Frailty was assessed by the Edmonton Frail Scale (EFS) with additional note of the Timed up and Go (TUG) which is one component of the EFS, gait velocity measured over four metres (metres per second) and hand grip strength. Due to concern about falls risk the TUG and gait velocity was recorded by a physiotherapist. Grip strength was recorded using a Jamar dynamometer according to the recommended protocol from the American Society of Hand Therapists which specifies a dominant hand, the position of the subject and dynamometer and a 'best of three' reading. The results were compared to published age and gender nomograms for hand grip strength [67 68]. The EFS was chosen for several reasons. First, it is brief which makes it attractive for translation into the routine clinical setting if the findings from these studies were to be implemented. Second, it has reasonable interrater reliability (Kappa=0.77, p=0.0001) and good internal consistency (Crohnbachs alpha=0.62) [48]. Third, it has been used in studies in the perioperative setting previously [69] and had face validity in its ability to highlight areas contributing to overall frailty that are potentially amenable to optimisation. This was important when considering the intervention study which this observational work was conducted to support.

Outcome measures

The primary outcome measure was length of hospital stay. This process measure has clear utility to clinicians and managers but was chosen in this study following the results of the stakeholder engagement work undertaken in the co-design of this study. This process and resultant outputs are described in 4.2. Secondary outcomes were postoperative morbidity (medical and surgical complications), functional status at hospital discharge (measured using TUG and gait velocity) and postoperative in-

hospital mortality. Complications were predefined prior to study recruitment and involved clinical findings and objective measures for each anticipated condition. For example, postoperative delirium was defined according to the Confusion Assessment Method and postoperative wound infection was defined as clinical evidence of infection such as erythema, fever, discharge from wound coupled with either positive microbiological findings on wound swab or use of new antibiotic prescription issued by the usual care team with the intention of managing wound infections. All outcomes measures were obtained through review of the medical notes and electronic records.

Reliability and feasibility measures

In a convenience sample of existing study subjects a small reliability analysis of the use of the MoCA was undertaken. This involved repeating the MoCA when patients reattended the hospital for routine surgical outpatient follow up and employed convenience sampling due to the limited availability of the researcher to reassess all patients during subsequent clinic visits. In this subgroup the repeat MoCA score performed at outpatient follow up was compared to the preoperative MoCA score. This was to examine whether the results obtained in the more acute ward environment when surgery was imminent, were an accurate representation of the patient's baseline cognition and not influenced by the potentially stressful situation or by delirium, which may have been missed due to clinical fluctuation at the time of recruitment. In addition, feasibility measures concerning the acceptability of MoCA to patients and the time taken to complete it were recorded in this subgroup. To assess feasibility, the time taken to perform MoCA, EFS and the number of participants who

completed the TUG and gait velocity was recorded. Reasons for non-completion were recorded and participant views on completing scores was noted.

Stakeholder co-design

According to the MRC guidance on evaluating complex interventions, the modelling phase involves engaging all stakeholders, refining the evaluation methodology and defining outcomes. Stakeholders in this observational phase of work included patients and their relatives or carers, vascular surgeons and nurses, vascular anaesthetists and critical care teams, preoperative clinic nurses, organ specific physicians, physiotherapists, occupational therapists and managers and administrators in all relevant clinical areas. These individuals were invited to take part in the co-design and co-production of the observational phase to clearly define existing issues, the intervention to be appraised and the evaluation study (described in chapter 5).

Engaging stakeholders

Different mechanisms were used to engage different groups. For example, vascular surgeons were approached at the departmental audit meeting where the work presented in chapters 2 and 3 was presented. Several subsequent meetings with surgical teams allowed for refinement of the observational study. Similarly, patient and public engagement was key in study design from the start. Patients who were inpatients on the vascular unit and their relatives and carers were approached and asked to contribute if they wished. They were also offered the opportunity to remain in contact with the research team as a virtual patient and public involvement (PPI) group (using telephone contact as well as face to face meetings) with the remit of

reviewing future written study materials and discussing ongoing work. This approach of a virtual ongoing group was chosen at the advice of the patients and public involvement lead at the Research Design Service, London due to the tertiary nature of vascular referrals into the recruiting centre and the potential frailty of the patient groups which meant that frequent trips to the hospital were impractical.

The process of co-design

Of particular relevance to this study was the influence that service users had over the primary outcome measure, inpatient length of stay. Whilst this commonly used outcome measure has utility for clinicians and managers, the patient representatives reported that spending as few days in hospital as possible was very important to them and their families. In addition, patients showed support for the proposed cognitive assessment process and reported that undertaking a brief cognitive assessment with a doctor would not be unduly stressful in the preoperative setting. Finally, the theme of delirium was identified as a particular concern to the patients who co-designed this phase of the research programme. Several of those involved and their families had unanswered questions about what delirium was, why it had occurred and felt it was important that the strong emotions they had about this recent experience were reflected in this programme of research. The study which resulted from this process is described in chapter 6. Engagement with all other stakeholders was instigated at this point in the research programme allowing for open dialogue and true co-design. For several of the stakeholders this ensured that re-engaging at the point of designing the intervention and evaluation study came from a place of pre-existing 'buy in' with the programme of work.

Data analysis

Data were analysed by SPSS version 20. The primary outcome measure, length of stay (days) was dichotomised at the mean, 12 days (despite, as anticipated, being skewed) as this was felt to have relevance to both clinicians and patients, relative and carers and resource implications in terms of significant financial cost. MoCA was dichotomised at <24 based on previous studies suggesting that at this point a diagnosis of minor neurocognitive disorder or mild cognitive impairment is probable [70]. EFS was defined by a cut off score of 6.5/17 as this was the mean value and also clinically relevant in that previous work has described relatively low EFS of 3/17 as relevant in highlighting an at risk elective surgical population and higher scores of 7/17 as being typical in geriatric medicine outpatient services where it is likely that the most frail and vulnerable patients are referred [48]. TUG was dichotomised at 20 seconds and gait velocity at 0.6 metres per second [71 72]. These relatively slow cut off points for these latter two measures were chosen, first, due to the inclusion in this study of patients with peripheral arterial disease who are known to have slower walking speeds and second, because this gait velocity has been shown to be associated with an increase in adverse postoperative outcomes [73 74].

Univariate analyses were performed first, between cognitive impairment defined by MoCA <24 and baseline and postoperative variables, and second, between EFS of 6.5, TUG of 20 seconds and gait velocity of less than 0.6 metres per second and baseline and postoperative variables. The strength of association between MoCA and EFS and the primary outcome measure, length of stay was examined using receiver operating characteristic (AUC) curves.

Limitations

The limitations in this observational study relate predominantly to research capacity. Whilst all attempts to recruit consecutive eligible participants was made, the lack of recruitment over weekends may have introduced bias in the sample. Finally, as described in section 1.2 an abnormal cognitive assessment score alone does not constitute a diagnosis of minor or major neurocognitive disorder. Whilst this limitation is accepted the abnormal MoCA score remains relevant as it suggests cognitive vulnerability predisposing to the likelihood of developing postoperative delirium and offering an opportunity for risk factor optimisation and ongoing follow up.

4.2 Results

These observational cohort studies are now presented in turn in the form of two published papers.

Contribution of each co-author to publication

Judith Partridge, Jugdeep Dhesi, Finbarr Martin and Danielle Harari conceived and designed this project resulting in the two publications presented in 4.2. Judith Partridge, Jason Cross and Matthew Fuller acquired data with analysis by Judith Partridge supported by Danielle Harari and Jessica Lo. Judith Partridge wrote the papers with Danielle Harari and Jugdeep Dhesi and critical revision of the articles was provided by Peter Taylor, Rachel Bell and Finbarr Martin.

The prevalence and impact of undiagnosed cognitive impairment in older vascular surgical patients

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Objective: **The objectives of this observational cohort study were to investigate the prevalence of undiagnosed cognitive impairment in older patients presenting for vascular surgery, to examine its association with adverse postoperative outcomes, and to test the feasibility of a preoperative cognitive assessment tool.**

Methods: **Patients aged 60 years or older were recruited by consent on admission to the vascular surgical ward of an inner-city teaching hospital with a large tertiary referral practice for proposed elective or emergency aortic or lower limb arterial intervention. Cognition was assessed preoperatively by the Montreal Cognitive Assessment (MoCA), and a score below 24/30 indicated cognitive impairment or dementia. The mean length of time taken to complete the assessment was recorded. Baseline characteristics (medical multimorbidity, frailty, and laboratory tests), hospital length of stay (LOS), and postoperative complications were documented.**

Results: **Preoperative MoCA was completed in 114 patients with a mean age of 76.3 years (standard deviation, 7.36 years); 67.5% were men, and 55.3% of procedures were elective. The MoCA was completed in 100% of patients and was quick and acceptable to patients in this setting. Cognitive impairment or dementia was found in 68% of patients (77 of 114) and was previously unrecognized in 88.3% of patients (68 of 77). Therefore, 60.5% of patients (68 of 114) aged 60 years or older presenting for vascular surgery had previously undiagnosed cognitive impairment. MoCA <24 was univariately associated with pre-existing frailty (Edmonton Frail Scale [EFS] score ≥6.5) and longer LOS (≥12 days). In logistic regression modeling, MoCA <24 was strongly independently associated with frailty EFS score ≥6.5 (odds ratio, 12.55; $P < .001$). By use of the area under the receiver operating characteristic curve (AUC), MoCA <24 was predictive of longer LOS of ≥12 days (AUC, 0.621; $P = .049$). The strength of predictive power increased with the addition of frailty (EFS score ≥6.5) to the models (AUC, 0.695; $P = .002$).**

Conclusions: **The prevalence of cognitive impairment among older patients presenting for vascular surgery is high and frequently undiagnosed before admission. It is feasible to use the MoCA to identify cognitive impairment in this high-risk surgical group preoperatively. The combined assessment of frailty and cognition is predictive of adverse postoperative outcomes and longer LOS. (J Vasc Surg 2014;60:1002-11.)**

The aging population together with surgical and anesthetic advances has resulted in increased numbers of older people having vascular procedures.[1] Whereas older patients benefit from vascular surgical procedures,[2] they remain at higher risk than younger patients of adverse postoperative outcomes.[3] These adverse outcomes include mortality and medical morbidity,[4] such as delirium,[5] and require greater resource use (longer hospital stay).[3]

Cognitive impairment predominates in the older population and can have a negative impact on postoperative outcomes. Patients with cognitive impairment are at increased risk of postoperative delirium[6] and protracted hospital length of stay (LOS) compared with the general hospital population.[7] Studies examining preoperative cognition with a neuropsychological test battery in older patients undergoing elective orthopedic surgery found amnestic mild cognitive impairment in 22%,[8] and 44% of elective abdominal and cardiothoracic surgery patients scored ≤3 on a preoperative Mini-Cog assessment.[9] However, the underlying disease and risk factors leading to orthopedic and abdominal surgery are not risk factors for cognitive problems. In comparison, risk factors for peripheral vascular disease (such as hypertension, hypercholesterolemia, and smoking) predispose to vascular cognitive impairment[10,11] and are independently associated with postoperative delirium.[5,12,13]

Identifying a cognitive assessment tool that is robust clinically for elective and emergency patients and for research purposes is important, as neither a full neurocognitive battery nor brief screening tools conform neatly to both requirements. The Montreal Cognitive Assessment (MoCA) is a 30-point assessment (Fig 1) that can be completed in 10 minutes; within a mixed study cohort of

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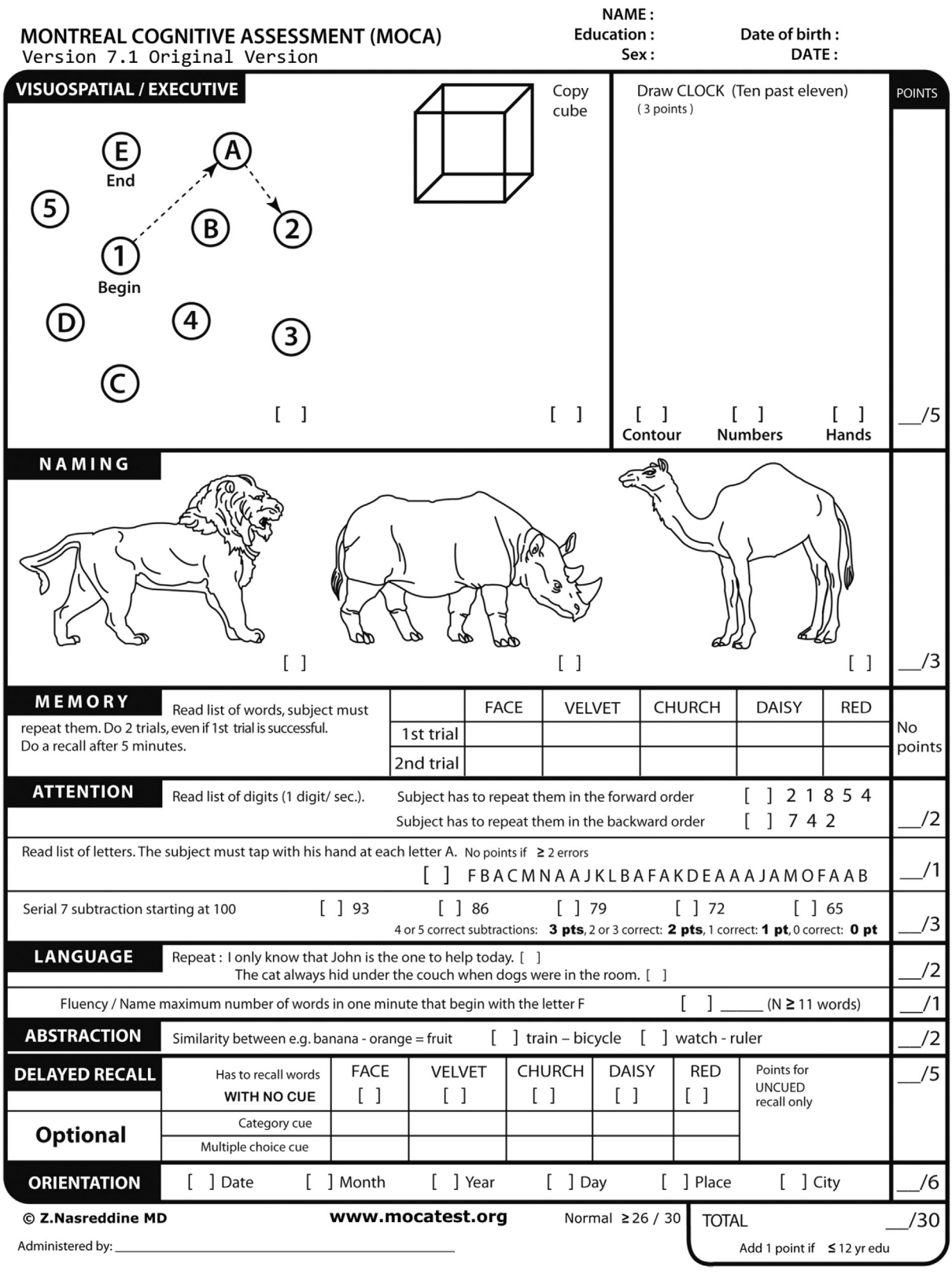

Fig 1. The Montreal Cognitive Assessment tool (MoCA). (Reproduced with permission from Nasreddine ZS, Phillips NA, Bedirian V, Charbonneau S, Whitehead V, Collin I, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. J Am Geriatr Soc 2005;53:695-9.)

patients with mild cognitive impairment, Alzheimer dementia, and community-dwelling controls, it shows high retest reliability (correlation coefficient, 0.92; $P < .001$) and internal consistency (Cronbach α, .83).[14] Sensitivity and specificity are superior to the Mini-Mental State Examination,[15] which until recently has been the short cognitive assessment of choice.[16,17] MoCA has been well validated in the identification of vascular cognitive impairment,[18] vascular dementia,[19] and mild cognitive impairment in patients with cardiovascular disease including heart failure[20] and in those with neurodegenerative conditions including Parkinson disease.[21] However, there is no literature describing the use of MoCA in the preoperative setting.

The aims of this study were to examine whether cognitive assessment with a short bedside assessment tool (MoCA) is clinically feasible within an older preoperative inpatient surgical population; to measure the proportion of older patients presenting for vascular surgery who have undiagnosed cognitive impairment; and to examine whether cognitive impairment, defined by MoCA score, is associated with a longer length of hospital stay.

METHODS

Ethical approval for the study was given in February 2011 by the South East Research Ethics Committee (11/H1102/10).

Setting

The study was conducted at an inner-city teaching hospital with a large tertiary referral practice for vascular surgery.

Subjects

Criteria for eligibility. Criteria for eligibility included age of 60 years or older in a patient presenting for elective or emergency aortic or lower limb arterial intervention.

Exclusion criteria. Patients receiving palliative treatment for a terminal condition were excluded, as were patients admitted and discharged over the weekend (because of unavailability of the researcher at this time).

Recruitment and consent. Patients were recruited within 48 hours of admission to the vascular surgical unit. Those without capacity to consent were handled according to sections 30-34 of the Mental Capacity Act (2005) employing the use of a personal consultee to give assent to study participation on behalf of the patient. The flow chart (Fig 2) shows details of patient recruitment.

Preoperative data collection

Baseline demographic data were collected through a combination of patient interview and review of clinical records. Comorbidities and medications were recorded. Frailty was assessed by the Edmonton Frail Scale (EFS),[22] defined by a cutoff score of ≥6.5/17.[23] Preoperative functional status was assessed by "timed up and go" [TUAG],[24] gait speed,[25] and grip strength recorded with a Jamar dynamometer, adhering to the standardized protocol recommended by the American Society of Hand Therapists.[26] TUAG was dichotomized at 20 seconds.[27,28] Gait speed was dichotomized at 0.6 m/s.[25,29,30] Hand grip strength was compared with accepted age and gender nomograms.[31] Anxiety and depression were assessed with the Hospital Anxiety and Depression Scale.[32]

Cognitive assessment

Clinical researchers assessed patients by the MoCA. Given the constraints of an acute surgical ward, all attempts were made to perform the assessment in a calm, quiet environment without interruption.

In addition, patients (and their carers or relatives) were asked if a diagnosis of dementia or any "memory problems" had been noted before. The clinical notes including correspondence were interrogated for any prior diagnosis or mention of cognitive impairment or dementia.

In-hospital data collection

Outcome measures including process indicators (LOS), postoperative morbidity (medical and surgical complications), postoperative functional status (assessed by TUAG and gait speed), and in-hospital mortality were recorded contemporaneously from the clinical record. Delirium was diagnosed by a researcher according to the Confusion Assessment Method.[33] Assessment for delirium was undertaken daily except on weekends. LOS ≥12 days was the mean LOS within this sample (which, as expected, was skewed) and was chosen as the cut point because it represented a significant resource use in terms of financial cost.

Feasibility of cognitive assessment

In a subgroup of 46 patients, the time taken to preoperatively complete the MoCA was recorded in minutes. A subset of 32 patients were reassessed cognitively with the MoCA at between 6 weeks and 4 months after hospitalization (mean of 73 days after hospital discharge). This convenience sample consisted of those patients who were routinely scheduled for and attended vascular outpatient clinics after their surgery. This subset was also asked in a semistructured manner for verbal feedback on their experience of the preoperative cognitive assessment undertaken as part of this study.

Data analysis

Data were analyzed by SPSS version 20 (IBM, Armonk, NY). Univariate analyses were performed between cognitive impairment, defined by a MoCA score dichotomized at <24,[20] and baseline and postoperative variables. Multiple logistic regression models were used to examine the strength of these associations with adjustment for potential confounders. Clinically relevant and statistically associated variables at the $P < .05$ level were included in the models. To ensure that highly correlated variables were not included in the regression models, variables were first examined for strength of correlation. Variables with a Pearson coefficient correlation of >0.6 were not both included in the models; where this situation arose, the variable of most clinical relevance was included.

The associations between LOS ≥12 days and baseline variables and postoperative outcomes were also examined

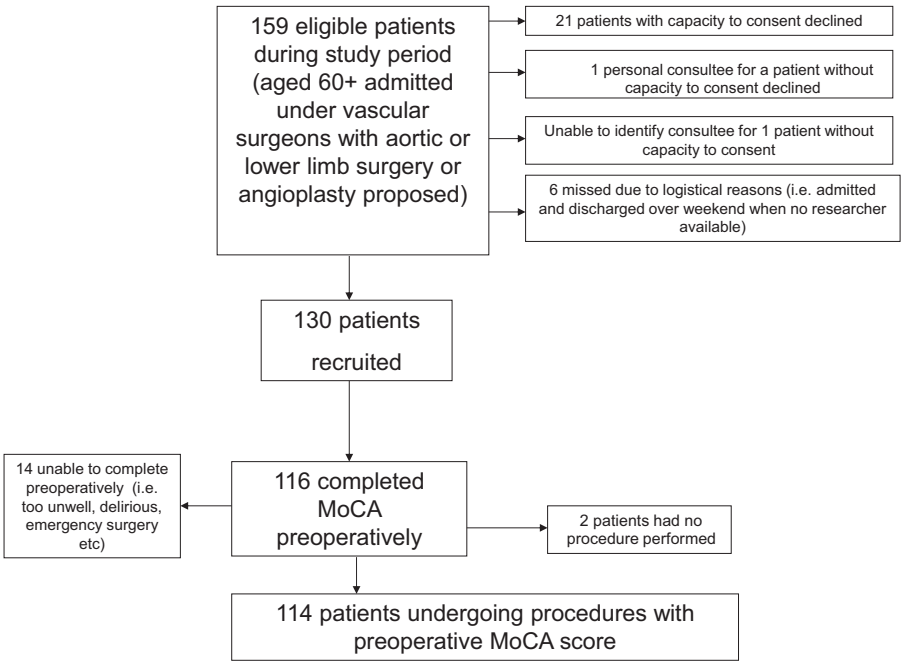

Fig 2. Flow chart. *MoCA*, Montreal Cognitive Assessment.

by univariate analyses. The strength of association between age, LOS ≥12 days, MoCA <24, and EFS score ≥6.5 was examined with the area under the receiver operating characteristic curve (AUC).

Paired *t*-tests were used to examine the association between cognitive scores at baseline and at outpatient follow-up in the subset of 32 patients.

RESULTS

The 114 patients were recruited and analyzed as shown in Fig 2. The mean age of patients was 76.3 years (standard deviation [SD], 7.36 years), and 67.5% were men. Eighty-nine percent of participants were white British according to the 2011 census categories. Mean length of full-time education was 10.6 years (SD, 2.18 years).

The study recruited patients as they presented to the vascular surgical ward and included those undergoing major open vascular surgery, endovascular procedures, and preoperative investigations (Table I).

Feasibility. The mean length of time taken to complete the MoCA was 9 minutes 41 seconds, and feedback from patients and their relatives followed up in the outpatient subset found this test acceptable in the preoperative setting. Thirty-two (28.1%) of the 114 patients preoperatively assessed with the MoCA completed the test for a second time within 21 to 167 days after discharge; the mean number of days from hospital discharge to follow-up cognitive assessment was 73 days (SD, 31.4 days). Comparison of MoCA score preoperatively and at follow-up showed no improvement or deterioration over time (paired *t*-test, −1.073; $P = .292$). Furthermore, the mean MoCA score in this subset of participants assessed at follow-up was 19.9 (SD, 5.95), showing no difference with the 20.8 (SD, 5.16) in the whole study cohort.

Of the 114 patients who underwent a procedure and completed the MoCA, 77 (67.5%) scored <24/30 on the examination. The mean MoCA score was 20.8 (SD, 5.16), with a range from 6 to 30. Only nine patients (7.9%) had any record of "dementia, cognitive impairment, memory problems, or confusion" in their medical notes or electronic hospital record and on discussion with the patient and relatives. Thus, no cognitive issue had been previously noted (or discussed with the patient or family) in 88.3% of patients (68 of 77) who scored <24 on the MoCA. In total, 60.5% of patients (68 of 114) aged 60+ years attending the hospital for vascular procedures had previously undiagnosed cognitive impairment. Of note, alcohol consumption in this population was low, with a mean weekly number of alcohol units consumed of 8.6 units (SD, 18.1 units) and the weekly median 1 unit. When dichotomized at various cutoff values, no univariate associations were seen with MoCA <24/30.

The incidence of impaired cognition (MoCA <24) according to age was as follows: aged 60 to 69 years, 50.0% (12 of 24); aged 70 to 79 years, 75.5% (37 of 49); aged 80+ years, 68.3% (28 of 41).

Clinically important and statistically significant baseline factors (Table II) associated with MoCA <24 were included in a multivariate logistic regression model. Independent associations between MoCA <24 and EFS score ≥6.5 (odds ratio, 8.41; $P = .001$) and diabetes (odds ratio, 4.79; $P = .029$) were observed (Supplementary Table I, online only).

Table I. Surgical procedures and urgency, route, and source of presentation to vascular surgical ward

Surgical procedures and urgency of presentation	*N = 114, No. (%)*
Type of procedure	
Imaging or investigation (eg, CTA with need for intravenous hydration and *N*-acetylcysteine cover, duplex ultrasound, angiography, bronchoscopy)	12 (10.5)
Angioplasty, thrombolysis, thrombectomy, embolectomy	25 (21.9)
Lower limb bypass graft	18 (15.8)
EVAR	40 (35.1)
Open AAA repair	4 (3.5)
Toe or foot amputation	3 (2.6)
Below-knee or through-knee amputation	2 (1.8)
Above-knee amputation	1 (0.9)
Other (eg, carotid-subclavian bypass, false aneurysm repair, evacuation of hematoma, débridement)	9 (7.9)
No. of procedures performed during admission	
Single procedure performed during admission	91 (79.8)
Two procedures performed during admission	2 (1.8)
Three or more procedures performed during admission	9 (7.9)
Referral source	
Elective vascular	63 (55.3)
Through emergency department	32 (28.1)
Admitted from clinic or radiology department	14 (12.3)
Transferred from other inpatient team	5 (4.4)
Local or tertiary	
Local boroughs	25 (21.9)
Neighboring boroughs	46 (40.4)
Farther afield	13 (37.7)

AAA, Abdominal aortic aneurysm; *CTA,* computed tomography angiography; *EVAR,* endovascular aneurysm repair.

Longer LOS (≥12 days) was univariately associated with MoCA <24. Other postoperative associations with MoCA <24 were wound infection, infection of any type, bowel and bladder complications (persistent maintenance of urinary catheter without documented clinical indication, urinary retention, constipation, and fecal incontinence), one or more postoperative medical complications (cardiac, respiratory, delirium, infective), and slow gait speed and TUAG at discharge (Table III).

Table IV shows the results of multiple logistic regression modeling to examine the association between MoCA <24 and longer LOS (≥12 days). To adjust the relationship between MoCA <24 and LOS ≥12 days, significantly associated baseline variables were included in the models (Supplementary Table I, online only). In this analysis, the strength of association between MoCA and LOS was less strong.

Several univariate associations were seen between LOS ≥12 days and baseline preoperative variables (Supplementary Table II, online only) and postoperative outcomes (Supplementary Table III, online only). Baseline characteristics showing univariate association with longer LOS (≥12 days) were those receiving home care, emergency presentation, MoCA <24, EFS score ≥6.5, and preoperative anemia. Postoperative events associated with longer LOS in univariate analysis were composite measures of postoperative bowel and bladder complications, postoperative infections, composite measure of postoperative complications, and composite measure of functional impairment (postoperative falls and dependent transfers at the third postoperative day).

MoCA <24 was associated with LOS ≥12 days and age by the AUC (0.621; confidence interval, 0.508-0.734; $P = .049$). This association between MoCA <24 and LOS ≥12 days was strengthened with the addition of EFS score ≥6.5 (AUC, 0.695; confidence interval, 0.584-0.806; $P = .002$). Table V shows the predictive ability of models examining longer LOS (≥12 days) when MoCA <24 and EFS score ≥6.5 are added. All analyses were age adjusted.

DISCUSSION

This observational study of 114 patients aged 60 years or older, undergoing elective and emergency aortic and lower limb arterial surgical procedures, demonstrated a significant burden of undiagnosed cognitive impairment. Demonstrating cognitive impairment within a high-risk group is important for several reasons.

First, cognitive impairment may have an impact on information provision and the process of informed consent and shared decision making preoperatively. Preoperative diagnosis may help clinicians more accurately describe perioperative risk, given that impaired cognition is associated with adverse in-hospital outcomes[9] and longer term postoperative outcomes.[34]

Second, vascular cognitive impairment confers an increased risk of postoperative delirium with its associated consequences[35,36] and longer length of hospital stay.[37] The risk of postoperative delirium is not routinely addressed in current preoperative services despite National Institute for Health and Clinical Excellence guidance, which endorses this approach.[38] Furthermore, evidence shows that simple interventions, such as optimizing sensory impairments and regularly reorienting patients, can reduce the incidence of delirium[39] if the risk of delirium is proactively highlighted.

Third, the National Dementia Strategy in England[40] advocates early diagnosis of cognitive impairment and dementia with provision of both medical investigation and intervention and adequate support services from the start of the illness. Whereas the merits of this approach have been debated recently,[41] this clearly has implications for a group shown to be at high risk. For these reasons, case finding by proactive examination of cognitive functioning in a high-risk population seems an appropriate step in preoperatively assessing older vascular surgical patients.

Older age was not significantly associated with MoCA <24 in this population, and 50% of participants aged 60 to 69 years scored <24 on the MoCA. Consensus estimates of the population prevalence of dementia in the United Kingdom suggest that only 1% of those aged 65 to 69 years have dementia.[42] The high rate of cognitive impairment seen at younger ages in this study may

Table II. Baseline preoperative variables and preoperative scores associated with Montreal Cognitive Assessment (*MoCA*) score <24 (univariate associations)

Baseline characteristics	*Cognition*		P *value*
	MoCA ≥ 24+ (n = 37) (32.5%), No. (%)	*MoCA <24 (n = 77) (67.5%), No. (%)*	
Age > 75 years	17 (45.9)	46 (59.7)	.165[a]
Gender (male)	25 (67.6)	52 (67.5)	.997
Marital status (married)	24 (64.9)	36 (48.0)	.092
Smoking status (ever smoked)	29 (78.4)	62 (84.0)	.465
≤10 years full-time education	19 (52.8)	45 (59.2)	.521
Hospital admission in preceding 12 months	20 (55.6)	47 (61.0)	.580
Receives home care	7 (18.9)	39 (50.6)	**.001**[a]
Lives alone	9 (24.3)	34 (44.2)	**.041**
Urgency of presentation (elective)	23 (62.2)	44 (57.1)	.610
On ≥6 medications	16 (43.2)	56 (73.7)	**.002**[a]
Ischemic heart disease	11 (29.7)	36 (46.8)	.084
Heart failure	2 (5.4)	11 (14.3)	.217[b]
Atrial fibrillation	7 (18.9)	21 (27.3)	.332
Hypertension	28 (75.7)	60 (78.9)	.694
Chronic lung disease	11 (29.7)	24 (31.2)	.876
Diabetes	3 (8.1)	26 (33.8)	**.003**[a,b]
Chronic kidney disease stage 3, 4, or 5	12 (32.4)	32 (41.6)	.349
Cerebrovascular disease	5 (13.5)	19 (24.7)	.171
Multisite vascular disease	9 (24.3)	37 (48.7)	**.013**[a]
Cancer	10 (27.0)	13 (16.9)	.206
Dementia/any note of cognitive issue	0 (0)	9 (11.7)	**.030**[b]
Depression	6 (16.2)	13 (16.9)	.929
Fall in last 6 months	9 (24.3)	24 (31.2)	.451
Visual impairment (visually impaired or blind)	37 (100.0)	72 (93.5)	.113
Hearing impairment	3 (8.3)	22 (28.6)	**.016**[b]
Urinary incontinence	7 (18.9)	16 (20.8)	.817
Fecal incontinence	5 (13.5)	6 (7.8)	.333
Self-reported weight loss	14 (38.9)	39 (52.0)	.195
Self-reported exhaustion	16 (43.2)	26 (33.8)	.326
Preoperative grip strength (below age- or gender-matched norms)	13 (39.4)	42 (60.0)	**.050**
Gait speed <0.6 m/s (preoperatively)	4 (14.3)	31 (59.6)	**<.001**[c]
TUAG ≥20 seconds (preoperatively)	4 (14.3)	26 (50.0)	**.002**[c]
EFS score ≥6.5	5 (13.9)	51 (66.2)	**<.001**[a]
HADS anxiety score 8+	8 (24.2)	14 (20.6)	.676
HADS depression score 8+	5 (15.2)	20 (29.4)	.119
Preoperatively anemic (hemoglobin <13 g/dL men and 12 g/dL women)	20 (54.1)	54 (70.1)	.092

EFS, Edmonton Frail Scale; *HADS,* Hospital Anxiety and Depression Scale; *TUAG,* timed up and go.
Bold values are statistically significant at the 5% level.
[a]Variable included in multiple logistic regression model.
[b]Cell count of less than 5, so Fisher exact test used in place of χ^2 test.
[c]Note different denominator because of 34 missing cases.

represent the prevalence of vascular cognitive impairment and vascular dementia as opposed to other dementias, such as Alzheimer disease, in a population with vascular risk factors, multisite vascular disease, and significant leukoaraiosis.[10,43] The lack of association seen between older age and MoCA <24 may be due to the increased mortality at younger ages of those with multiple vascular risk factors.[44]

The literature validating MoCA as a short assessment tool in several different patient groups has proliferated in the last 2 years. When the MoCA was first described, the authors used a cutoff score of <26/30 to define mild cognitive impairment as validated by a neuropsychological battery, and the MoCA showed a sensitivity of 90% and specificity of 87%.[14] For Alzheimer dementia compared with the same neuropsychological battery, the MoCA showed sensitivity of 100% and specificity of 87%. More recent studies propose a cutoff value of 24/30 in patients with cardiovascular disease and diabetes, with preserved sensitivity and specificity compared with the Neuropsychological Assessment Battery Screening Module.[20] The MoCA was chosen for this study on clinical grounds as it is better than the Mini-Mental State Examination in assessing the executive dysfunction known to predominate in those with vascular cognitive impairment.[45,46] In terms of accessibility, the MoCA is available in 36 languages and validated in 21 languages, and there is a version for those who are visually impaired. In addition, the standard MoCA is scored according to years of education, and the MoCA basic for those with lower educational attainment or illiteracy is in development. This is relevant to this

Table III. Postoperative outcomes associated with Montreal Cognitive Assessment (*MoCA*) score <24 (univariate associations)

	Cognition		
Postoperative outcomes	*MoCA ≥ 24 (n = 37) (32.5%), No. (%)*	*MoCA <24 (n = 77) (67.5%), No. (%)*	P *value*
Postoperative delirium	4 (10.8)	16 (20.8)	.293[a]
Pneumonia	2 (5.4)	6 (7.8)	1.00[a]
Acute coronary syndrome	2 (5.4)	5 (6.5)	1.00[a]
Arrhythmia	2 (5.4)	6 (7.8)	1.00[a]
Heart failure	0 (0)	3 (3.9)	.550[a]
Fall on ward	1 (2.7)	10 (13.0)	.100[a]
Urinary tract infection	1 (2.7)	4 (5.2)	1.00[a]
Wound infection	0 (0)	15 (19.5)	**.002**[a]
Catheter without clinical indication documented	1 (2.7)	10 (13.0)	.100[a]
Urinary retention	0 (0)	5 (6.5)	.172[a]
Constipation	3 (8.1)	7 (9.1)	1.00[a]
Fecal incontinence	2 (5.4)	13 (16.9)	.138[a]
Dependent transfers postoperative day 3	8 (25.0)	27 (37.0)	.230
Composite postoperative bowel and bladder complications	5 (13.5)	24 (31.2)	**.043**[b,c]
Composite postoperative infective complications	3 (8.1)	23 (29.9)	**.009**[a,d]
Composite postoperative complications	9 (24.3)	35 (44.2)	**.041**[b,e]
Composite postoperative functional issues	13 (35.1)	34 (44.2)	.360[f]
TUAG at discharge of ≥20 seconds	8 (30.8)	33 (62.3)	**.008**[g]
Gait speed at discharge of <0.6 m/s	8 (30.8)	37 (71.2)	**.001**[h]
In-hospital mortality	2 (5.4)	2 (2.6)	.594[a]
LOS ≥12 days	5 (13.5)	25 (32.5)	**.031**[b]
LOS ≥10 days	9 (24.3)	34 (44.2)	**.041**

LOS, Length of stay; *TUAG*, timed up and go.
Bold values are statistically significant at the 5% level.
[a]Cell count of less than 5, so Fisher exact test used in place of χ^2 test.
[b]Variables included in multiple linear regression.
[c]Composite variable including postoperative catheter without clinical indication documented, urinary retention, constipation, fecal incontinence.
[d]Composite variable including postoperative pneumonia, urinary tract infection, wound infection.
[e]Composite variable including postoperative delirium, pneumonia, acute coronary syndrome, arrhythmia, heart failure, urinary tract infection, wound infection.
[f]Composite variable including fall on ward and dependent transfers at postoperative day 3.
[g]Note different denominator because of 36 missing cases.
[h]Note different denominator because of 35 missing cases.

Table IV. Postoperative outcomes associated with Montreal Cognitive Assessment (*MoCA*) score <24 adjusted for significant baseline associations and age

Postoperative outcomes associated with MoCA <24 adjusted for significant baseline associations	*Adjusted odds ratio*	*95% Confidence interval*	P *value*
Age >75 years	2.99	1.01-8.89	**.049**
Diabetes	5.89	1.36-25.58	**.018**
EFS score ≥6.5	12.55	3.83-41.15	**<.001**
Composite postoperative bowel and bladder complications	4.32	0.96-19.50	.057
Composite postoperative complications	1.53	0.47-4.97	.484
LOS ≥12 days	1.05	0.25-4.38	.950

EFS, Edmonton Frail Scale; *LOS*, length of stay.
Bold values are statistically significant at the 5% level.

patient group as the mean number of years spent in full-time education was just 10.4 years (SD, 2.29 years).

Strong associations were seen between MoCA <24 and EFS score ≥6.5. In combination, these measures of impaired cognition and frailty were more strongly predictive of longer LOS than they were separately. This is not surprising, given our knowledge about the coexistence of geriatric syndromes[47,48] and the causative role of vascular risk factors in frailty, vascular cognitive impairment, and vascular dementia.[49] The strength of the relationship between longer LOS (>12 days) and MoCA <24 and EFS score ≥6.5 is particularly relevant clinically where preoperative identification of vascular cognitive impairment, dementia, and frailty may facilitate perioperative risk prediction and optimization to modify this risk.

Table V. Area under receiver operating characteristic curve (*AUC*) by predictor of longer hospital stay (LOS ≥12 days)

Adjustment	*AUC*	*95% Confidence interval*	P *value*
Age >75 years and MoCA <24	0.621	0.508-0.734	**.049**
Age >75 years and EFS score ≥6.5	0.660	0.541-0.779	**.010**
Age >75 years, MoCA <24, and EFS ≥6.5	0.695	0.584-0.806	**.002**

EFS, Edmonton Frail Scale; *LOS,* length of stay; *MoCA,* Montreal Cognitive Assessment.
Bold values are statistically significant at the 5% level.

Limitations. The results of this study may be influenced by several factors. Whereas cognitive impairment was frequently observed with MoCA, this was not compared with a neurocognitive battery or a memory clinic diagnosis of vascular cognitive impairment or dementia. MoCA has, however, been validated against neurocognitive assessment in previous work,[50] particularly in patients after stroke, who have profiles of vascular risk similar to those of the surgical population in this study.

The 2- to 3-month follow-up MoCA evaluation was potentially biased as fitter patients or those with less cognitive impairment are more likely to attend follow-up appointments, and those with more complex surgical needs may be preferentially invited back as outpatients. However, analysis of this small subset was representative of the overall sample in terms of other baseline characteristics. The study observation that preoperative cognitive impairment remained stable at 2- to 3-month follow-up may support the accuracy of MoCA as a preoperative cognitive assessment tool, albeit with the acknowledgment that use of a convenience sample can introduce systemic bias. This conclusion could therefore not be extrapolated to the whole study population.

Whereas all attempts were made to perform the preoperative cognitive assessment without interruption, both the physical environment and the concern from patients regarding impending surgery may potentially affect cognitive test results. However, the follow-up cognitive assessments were performed in a quiet room in the outpatient setting without interruption or operation-related anxiety, with similar case-by-case results. Again, the likely systematic bias from the sampling method should be acknowledged here.

Exclusion of potential participants admitted and discharged over the weekend also introduces potential sampling bias in the whole study cohort. Consecutive patients were eligible for participation, however, and it is very rare for older vascular surgical patients to be admitted and discharged in such a short time frame.

As expected, LOS data were skewed. Whereas there are inherent issues with use of skewed data, the mean value of 12 days was deemed to be clinically pertinent as it is closely associated with considerable resource use.

Finally, although the study showed a 20% incidence of postoperative delirium, this may be an underestimation because of the fluctuant nature of the condition and the single researcher performing the Confusion Assessment Method once daily on weekdays only. The lack of statistical association seen between postoperative delirium and preoperative cognitive impairment in this work is surprising. It is probable that this is due in part to a mixed cohort of surgical procedures included in the study. For example, although the underlying vascular risk factors are comparable between patients and therefore make the presence of cognitive impairment equally likely between participants, patients undergoing relatively minor procedures, such as angioplasty, are at lower risk of postoperative delirium than those undergoing open abdominal aortic aneurysm repair. The lack of association between postoperative delirium and cognitive impairment is therefore likely to represent a type II error.

CONCLUSIONS

The frequency of vascular risk factors in older vascular surgical patients and the high prevalence of previously unrecognized cognitive impairment demonstrated in this observational study suggest that preoperative examination for cognitive impairment should be incorporated into standard preoperative assessment of at-risk patients. The MoCA was a clinically feasible tool for preoperative use in both elective and emergency surgical patients. Establishing the MoCA in routine preoperative pathways could promote considered handling of consent and capacity; proactive identification and modification of delirium risk; and examination of underlying causes for cognitive decline, risk factor management, and early onward referral to specialist memory services.

The strong association between cognitive impairment and frailty may be clinically useful in highlighting potential areas for preoperative modification of risk to reduce adverse postoperative outcomes, including prolonged LOS. Future research should examine the feasibility and impact of preoperative services that incorporate cognitive assessment and optimization and provision of information to older patients into routine care pathways.

AUTHOR CONTRIBUTIONS

Conception and design: JP, JD, FM, DH
Analysis and interpretation: JP, JD, FM, DH
Data collection: JP, JC
Writing the article: JP, JD, DH
Critical revision of the article: PT, RB, FM
Final approval of the article: DH
Statistical analysis: JL, JP, DH
Obtained funding: JP, JD, FM, DH
Overall responsibility: DH

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Supplementary Table I (online only). Baseline characteristics independently associated with Montreal Cognitive Assessment (*MoCA*) score <24/30

Baseline variables associated with MoCA <24[a]	*Adjusted odds ratio*	*95% Confidence interval*	P *value*
Age >75 years	1.85	0.67-5.12	.239
Home care	1.12	0.35-4.09	.785
Medications 6+	1.25	0.45-3.49	.676
Multisite vascular disease	2.02	0.71-5.74	.185
Diabetes	**4.78**	1.17-19.53	**.029**
EFS score ≥6.5	**8.41**	2.38-29.70	**.001**

EFS, Edmonton Frail Scale.
Bold values are statistically significant at the 5% level.
[a]Hearing impairment and gait speed and timed up and go, although significantly associated with MoCA <24 in the univariate associations, were not included in this model because of a low number of cases and missing data, respectively.

Supplementary Table II (online only). Preoperative factors associated with length of stay (*LOS*) ≥12 days (univariate analyses)

Baseline characteristics	*LOS*		P *value*
	LOS < 12 days (n = 84) (73.7%), No. (%)	*LOS ≥ 12 days (n = 30) (26.3%), No. (%)*	
Age >75 years	45 (53.6)	18 (60.0)	.543
Gender (male)	60 (71.4)	17 (56.7)	.138
Marital status (married)	47 (56.6)	13 (44.8)	.273
Smoking status (ever smoked)	66 (79.5)	26 (89.7)	.220
Had ≤10 years full-time education	49 (59.8)	15 (50.0)	.356
Admitted to hospital in last 12 months	48 (57.1)	19 (65.5)	.429
Has home care	27 (32.1)	19 (63.3)	**.003**
Lives alone	29 (34.5)	14 (46.7)	.239
Urgency of presentation (elective)	59 (70.2)	8 (26.7)	**<.001**
On 6+ medications	49 (58.3)	23 (79.3)	**.043**
Ischemic heart disease	33 (39.3)	14 (46.7)	.481
Heart failure	6 (7.1)	7 (23.3)	**.017**
Atrial fibrillation	19 (22.6)	9 (30.0)	.420
Hypertension	67 (79.8)	21 (72.4)	.411
Chronic lung disease	23 (27.4)	12 (40.0)	.198
Diabetes	19 (22.6)	10 (33.3)	.247
Chronic kidney disease stage 3A or worse	31 (36.9)	13 (43.3)	.535
Cerebrovascular disease (previous stroke or transient ischemic attack)	19 (22.6)	5 (16.7)	.492
Multisite vascular disease	30 (35.7)	16 (55.2)	.066
Cancer	19 (22.6)	4 (13.3)	.277
Dementia or cognitive issues	6 (7.1)	3 (10.0)	.618[a]
History of depression documented	16 (19.0)	3 (10.0)	.254[a]
Fall in last 6 months	25 (29.8)	8 (26.7)	.748
Visual impairment (visually impaired or blind)	82 (97.6)	27 (90.0)	.080
Hearing impairment	13 (15.7)	12 (40.0)	**.006**
Self-reported weight loss	31 (37.8)	22 (75.9)	**<.001**[b]
Self-reported exhaustion	30 (35.7)	12 (40.0)	.676
Urinary incontinence	15 (17.9)	8 (26.2)	.302
Fecal incontinence	10 (11.9)	1 (3.3)	.172[a]
Preoperative grip strength (below age- or gender-matched norms)	38 (48.7)	17 (68.0)	.093[c]
MoCA <24	52 (61.9)	25 (83.3)	**.031**
TUAG ≥ 20 seconds	21 (33.3)	9 (52.9)	.138[d]
Gait speed <0.6 m/s	23 (36.5)	12 (70.6)	**.012**[d]
EFS score ≥6.5	35 (41.7)	21 (72.4)	**.004**[e]
HADS anxiety score 8+	17 (22.4)	5 (20.0)	.803[f]
HADS depression score 8+	15 (19.7)	10 (40.0)	**.042**[f]
Preoperatively anemic (hemoglobin <13 g/dL men and 12 g/dL women)	49 (58.3)	25 (83.3)	**.014**

EFS, Edmonton Frail Scale; *HADS*, Hospital Anxiety and Depression Scale; *MoCA*, Montreal Cognitive Assessment; *TUAG*, timed up and go.
Bold values are statistically significant at the 5% level.
[a]Cell count of less than 5, so Fisher exact test used in place of χ^2 test.
[b]Note different denominator because of three missing cases.
[c]Note different denominator because of 11 missing cases.
[d]Note different denominator because of 34 missing cases.
[e]Note different denominator because of one missing case.
[f]Note different denominator because of 13 missing cases.

Supplementary Table III (online only). Postoperative outcomes associated with length of stay (*LOS*) ≥12 days (univariate analyses)

	LOS		
Postoperative outcomes	*LOS < 12 days (n = 84) (73.7%), No. (%)*	*LOS ≥ 12 days (n = 30) (26.3%), No. (%)*	P *value*
Postoperative delirium	10 (11.9)	10 (33.3)	**.008**
Pneumonia	3 (3.6)	5 (16.7)	**.029**[a]
Acute coronary syndrome	3 (3.6)	4 (13.3)	.077[a]
Arrhythmia	4 (4.8)	4 (13.3)	.204[a]
Heart failure	0 (0)	3 (10.0)	**.017**[a]
Fall on ward	5 (6.0)	6 (20.0)	**.025**
Dependent transfers postoperative day 3	11 (14.5)	24 (82.8)	**<.001**
Urinary tract infection	2 (2.4)	3 (10.0)	.113[a]
Wound infection	5 (6.0)	10 (33.3)	**<.001**
Catheter without clinical indication documented	3 (3.6)	8 (26.7)	**.001**[a]
Urinary retention	4 (4.8)	1 (3.3)	1.000[a]
Constipation	6 (7.1)	4 (13.3)	.451[a]
Fecal incontinence	3 (3.6)	12 (40.0)	**<.001**[a]
Composite postoperative bowel and bladder complications	12 (14.3)	17 (56.7)	**<.001**
Composite postoperative infective complications	10 (11.9)	16 (53.3)	**<.001**
Composite postoperative complications	22 (26.2)	21 (70.0)	**<.001**
Composite adverse postoperative functional outcomes	22 (26.2)	25 (83.3)	**<.001**
Discharge TUAG ≥20 seconds	25 (41.0)	16 (88.9)	**<.001**[b]
Discharge gait speed <0.6 m/s	28 (45.9)	17 (100.0)	**<.001**[c]
In-hospital mortality	0 (0)	4 (13.3)	**.004**[a]

TUAG, Timed up and go.

Bold values are statistically significant at the 5% level.

[a]Cell count of less than 5, so Fisher exact test used in place of χ^2 test.

[b]Note different denominator because of 35 missing cases.

[c]Note different denominator because of 36 missing cases.

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Original research

Frailty and poor functional status are common in arterial vascular surgical patients and affect postoperative outcomes

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HIGHLIGHTS

- Frailty is common in older patients undergoing arterial vascular surgery.
- The Edmonton Frail Scale (EFS) was a feasible tool for the preoperative assessment of frailty.
- The EFS in older vascular surgical patients was high compared with other elective surgical groups.
- An EFS of ≥6.5 was predictive of longer length of hospital stay.

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ABSTRACT

Objectives: Increasing numbers of older people are undergoing emergency and elective arterial vascular procedures. Many older patients are frail which is a recognised predictor of adverse postoperative outcomes in other surgical specialties. This study in older patients undergoing arterial vascular surgery examined; the prevalence of preoperative frailty; the clinical feasibility of preoperatively measuring frailty and functional status; the association between these characteristics and adverse postoperative outcome.
Methods: Prospective observational study in patients aged over 60 years undergoing elective and emergency arterial vascular surgery. Baseline measures of frailty (Edmonton Frail Scale), functional status (gait velocity, timed up and go, hand grip strength) and cognitive function (Montreal Cognitive Assessment) were obtained preoperatively. The primary outcome measure Length of Stay (LOS) and secondary outcome measures of postoperative morbidity (medical and surgical complications), functional status and postoperative in-hospital mortality were recorded.
Results: 125 patients were recruited. Frailty was common in this older surgical population (52% EFS score of ≥6.5) with high frailty scores observed (mean EFS 6.6, SD 3.05) and poor functional status (60% had TUG >15 s, 45% had gait velocity of <0.6 m/s). Higher preoperative EFS (>6.5) was univariately associated with longer LOS (≥12 days), composite measures of postoperative infections, postoperative medical complications and adverse functional outcomes. EFS≥6.5 was predictive of LOS≥12 days, adjusted for age (AUC 0.660, CI 0.541–0.779, $p = 0.010$). This association between EFS ≥ 6.5 and LOS ≥ 12 days was strengthened with the addition of MoCA < 24 (AUC 0.695, CI 0.584–0.806, $p = 0.002$).
Conclusions: Patients aged over 60 years admitted for arterial vascular surgery were frail, had impaired functional status and were cognitively impaired. This combination of preoperative characteristics was predictive of longer hospital length of stay and associated with adverse postoperative outcome.

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1. Introduction

Vascular services are managing increasing numbers of older patients as the population ages and evidence accrues of the benefit from arterial vascular surgery in older people [1]. This poses a challenge as increasing age is associated with physiological changes, multi-morbidity and specific geriatric syndromes which increase the risk of adverse postoperative outcomes [2–4]. Risk factors (including hypertension, hypercholesterolemia and cigarette smoking) which predispose to the development of peripheral vascular disease and aortic aneurysms, also predispose to frailty [5,6]. Frailty is defined as physiological decline across multiple organ systems, making the patient vulnerable to even relatively minor external stressors [7–9]. It is an independent predictor of postoperative morbidity, postoperative mortality, length of stay (LOS) and institutionalisation at discharge [10–16]. However, although functional status has been reported as a predictor of adverse postoperative outcome in those with lower limb arterial disease undergoing revascularisation [17,18], the prevalence of frailty and its impact on postoperative outcomes has not been studied more widely in older patients undergoing planned and unplanned aortic and lower limb surgery.

Numerous measures of frailty exist, from scales, scores and indices to functional measures such as "timed up and go" (TUG) and gait velocity. These have prognostic value in various clinical settings. The Edmonton Frailty Scale (EFS) [19] is validated when used in the preoperative setting for elective surgical patients [14], high EFS scores being associated with both postoperative complications and prolonged LOS. It is a short tool based on 11 questions covering nine domains, scored from zero to 17, the maximum frailty score [19]. Thus the EFS may be useful to identify risk profiles preoperatively, potentially enabling modification of risk and better postoperative outcomes.

The aims of this observational study were to examine in elective and emergency arterial vascular surgical patients;

1. The clinical feasibility of pre and postoperative assessment of frailty and functional status using EFS, TUG, gait velocity and hand grip strength.
2. The prevalence of preoperative frailty.
3. The association between preoperative frailty, preoperative physical function and adverse postoperative outcome

2. Methods

Approval for the study was given in February 2011 by the South East Research Ethics Committee (11/H1102/10). This study has been described previously [20].

2.1. Setting

The study was conducted at a single institution; an inner city teaching hospital which operates as a hub centre providing care to both the local population and with a large tertiary referral practice for vascular surgery as is increasingly the practice in the UK.

2.2. Subjects

2.2.1. Criteria for eligibility

1. Aged 60 years or more.
2. Presenting for proposed elective or emergency aortic or lower limb arterial intervention.

2.2.2. Exclusion criteria

1. Patients receiving palliative treatment for a terminal condition.
2. Patients admitted and discharged over the weekend (research team capacity).
3. Patients too unwell to complete the preoperative assessments.

2.2.3. Recruitment and consent

The study was open to recruitment from May until August 2011. Patients were consecutively recruited within 48 h of admission to the vascular surgical unit. Written informed consent was sought. Participation of those without capacity to consent was managed according to sections 30–34 of the Mental Capacity Act (2005) employing the use of a personal consultee to give assent to study participation on behalf of the patient. Flow chart (Fig. 1) shows details of patient recruitment. A sample size of 120 was required based on the statistical necessity of 7–10 cases per variable anticipated for the regression modelling.

2.2.4. Preoperative data collection

Baseline demographic data were collected through a combination of patient interview and review of medical records. Comorbidities including falls history, medications and social history were recorded. Clinical assessment of frailty and cognition (Montreal Cognitive Assessment, MoCA) [21] were undertaken preoperatively by a trained clinical researcher. The Hospital Anxiety and Depression Scale (HADS) [22] was also completed preoperatively.

2.2.5. Frailty and functional assessments

2.2.5.1. Edmonton Frail Scale (EFS). The EFS assesses nine domains of frailty (cognition, general health status, functional independence, social support, medication usage, nutrition, mood, continence, functional performance) and provides a score from 0 to 17 where 17 represents the maximum level of frailty [19] (appendix 1). It incorporates the "timed up and go" test (TUG), with the option of a maximum domain score of 2 for participants unwilling or unable to perform it. Frail and non-frail participants were defined according to dichotomising the EFS score at 0–6 and 7–17.

2.2.5.2. Grip strength. Hand grip strength was assessed preoperatively using a Jamar dynamometer adhering to the standardised protocol recommended by the American Society of Hand Therapists [23]. The result was compared with accepted age and gender nomograms [24].

2.2.5.3. Gait velocity & TUG. A physiotherapist preoperatively recorded gait velocity and TUG. Gait velocity is walking velocity over four metres. TUG asks a seated subject to rise from a chair, walk a distance of three metres, turn round and return to sit in the chair. TUG was dichotomised at 20 s [25,26] and gait velocity at 0.6 m/s [25–28].

2.2.6. Postoperative data collection

Outcomes including the primary outcome measure LOS and secondary measures of postoperative morbidity (medical, surgical and functional complications), functional status at discharge (TUG and gait velocity) and postoperative in-hospital mortality were recorded contemporaneously from the medical record until the patient was discharged from hospital or died in hospital. Complications were predefined prior to study commencement and involved objective measures coupled with clinical findings. For example postoperative acute coronary syndrome was defined as clinical features coupled with ECG and troponin changes for which low molecular weight heparin was given, and postoperative wound

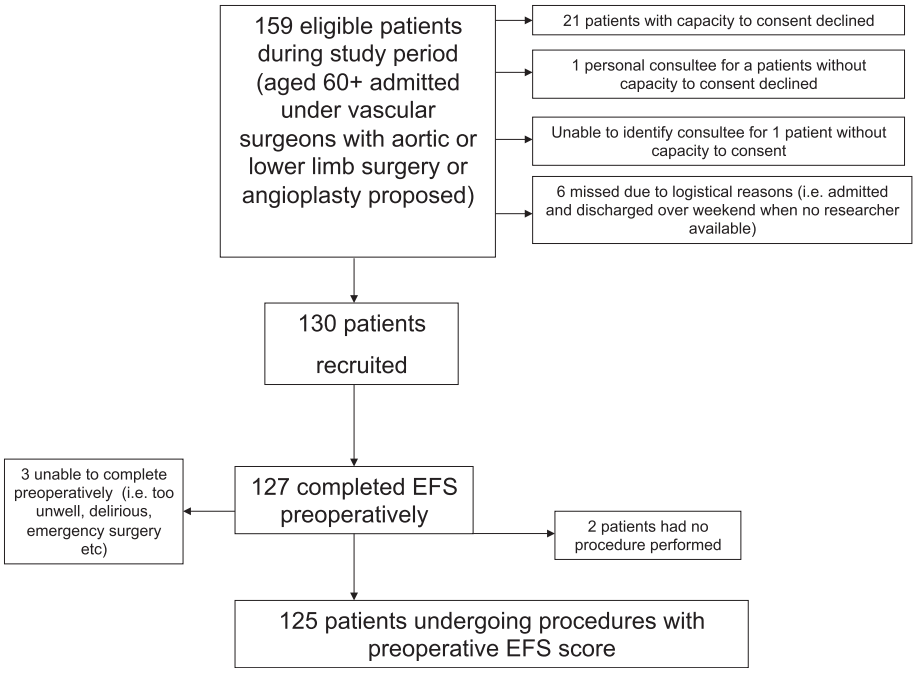

Fig. 1. Flowchart of study recruitment.

infection was defined as clinical features of infection coupled with positive culture on wound swab and prescription of relevant antibiotics Postoperative delirium was diagnosed according to the Confusion Assessment Method [29]. This was performed daily with the exception of weekends. Twelve days was the mean LOS within this sample (which was positively skewed) and was used as the cut off point because of the significant resource use in terms of financial cost.

2.2.7. Feasibility of frailty and functional assessment

The number of participants who completed each assessment (EFS, grip strength, TUG and gait velocity) was recorded. Reasons for non-completion were noted.

2.2.8. Data analysis

Data was analysed using SPSS version 20. Univariate analyses were performed between the dichotomised EFS, TUG and gait velocities and baseline and postoperative variables. Multiple logistic regression models were used to examine the strength of these associations adjusting for potential confounders. Clinically relevant and statistically associated variables at the $p < 0.05$ level were included in the models. To ensure that highly correlated variables were not included in the regression models variables were first examined for strength of correlation. Variables with a Pearson's coefficient correlation of >0.6 were not both included in the models; where this situation arose the variable of most clinical relevance was included.

The association between LOS ≥12days and baseline variables and postoperative outcomes was also examined using univariate analyses. The strength of association between age, LOS ≥12, EFS ≥6.5 and MoCA<24 was examined using area under the curve (AUC). These dichotomisation points were chosen for both clinical and statistical reasons based on existing literature. Clinically a LOS of 12 days has significant implications in terms of patient experience and resource use and whilst EFS of 6.5 is higher than seen in other elective surgical groups this is representative of the frail vascular population. Literature validating a MoCA cut off of 24 is growing [30] and was clinically meaningful in a sample with limited years of full time education. Similar numbers of cases in both groups aided regression analysis.

3. Results

125 patients were recruited and analysed as shown in Fig. 1.

The mean age of participants was 76.3 years (SD 7.27), 68.8% were male and 87% were white British. Table 1 shows their mode of presentation and the procedures conducted.

3.1. Feasibility

The EFS took less than 5 min to perform. If the time taken to perform TUG was excluded it took less than a minute to complete.

The mean EFS in the 125 participants who completed the score was 6.6 (SD 3.05, range 0–14). Fig. 2 shows the EFS score according to age categories.

In 69 of the 125 patients (55%) TUG and gait velocity were assessed both preoperatively and at hospital discharge. Reasons for failure to obtain these included; [a] too unwell or unsafe to mobilise, [b] discharge over a weekend, [c] amputation, [d] bedbound at discharge, [e] death in hospital. Preoperatively mean TUG was 22.2 s (SD 18.18) and mean gait velocity was 0.68 m/s (SD 0.31) (Table 2).

3.2. Analysis of preoperative variables

Clinically important and statistically significant baseline factors (Table 3) associated with EFS ≥6.5 were included in a multivariate logistic regression model. Independent associations between EFS ≥6.5 included emergency admission, being in receipt of preoperative care package, taking ≥6 medications and cognitive impairment defined as MoCA score of <24 (appendix 2).

Table 1
Surgical procedures and urgency and route of presentation to vascular surgical ward.

Surgical procedure(s) and urgency of presentation	n = 125(%)
Type of procedure	
Imaging/investigation e.g. CTA with need for ICI and NAC, duplex, angiogram, bronchoscopy	12 (9.6%)
Angioplasty/thrombolysis/thrombectomy/embolectomy	29 (23.2%)
Lower limb bypass graft	21 (16.8%)
EVAR	44 (35.2%)
Open AAA repair	5 (4.0%)
Toe/foot amputation	3 (2.4%)
BKA/TKA	2 (1.6%)
AKA	1 (0.8%)
Other (e.g. pseudoaneurysm repair, evacuation haematoma etc	8 (6.4%)
No. of procedures performed during admission	
Single procedure performed during admission	101 (80.8%)
Two procedures performed during admission	3 (2.4%)
Three or more procedures performed during admission	9 (7.2%)
Referral source	
Elective vascular	66 (52.8%)
Through emergency department	40 (32.0%)
Admitted from clinic/radiology	14 (11.2%)
Transferred from other inpatient team	5 (4.0%)
Local or tertiary	
Local boroughs	26 (20.8%)
Neighbouring boroughs	55 (44.0%)
Further afield	44 (35.2%)

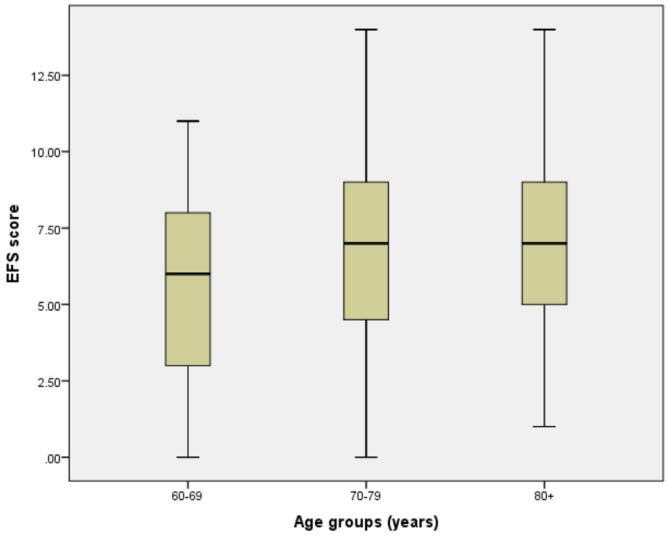

Fig. 2. Edmonton Frail Scale according to age group in older arterial vascular surgical patients.

Table 2
Number of participants completing each functional/frailty assessment and the mean value.

Frailty measure	No. completing assessment	Mean value (SD)
EFS (score/17)	125	6.6 (3.05)
Grip strength (kg)	107	27.02 (11.33)
Timed up and go, TUG (seconds)	84	22.20 (18.18)
Gait speed (m/s)	84	0.68 (0.31)

3.3. Univariate analyses

Preoperative EFS ≥6.5 was univariately associated with longer LOS (≥12 days), wound infection, composite measures of postoperative infections, postoperative complications, adverse functional outcomes (fall on ward and dependent transfers at postoperative day 3) and postoperative faecal incontinence (Table 4). Of note the majority of patients were discharged to their usual place of residence with only 7/125 (6%) going to either a local hospital or bed-based rehabilitation unit at discharge.

Similar associations as those seen between preoperative EFS were seen when preoperative TUG, gait velocity and hand grip strength were univariately analysed with baseline variables (appendix 3,4,5) and postoperative outcomes (appendix 6,7,8).

Several univariate associations were seen between LOS≥12 and preoperative variables (appendix 9) namely receiving homecare, emergency presentation, MoCA <24, EFS ≥6.5, preoperative anaemia and postoperative outcomes (appendix 10) namely composite measures of postoperative bowel and bladder complications, postoperative infections, composite measure of postoperative complications, composite measure functional impairment (postoperative falls and dependent transfers at the third postoperative day) and slower TUG and gait velocity at hospital discharge.

3.3.1. Multivariate analyses

Table 5 shows the results of multiple logistic regression modelling to examine the association between EFS ≥ 6.5 and longer LOS ≥ 12 days.

To adjust the relationship between EFS ≥ 6.5 and LOS ≥ 12 days significantly associated baseline variables were included in the model. In this analysis the strength of association between EFS ≥ 6.5 and LOS ≥ 12 was weaker.

3.4. AUROC analysis

EFS ≥ 6.5 was associated with LOS ≥ 12 days and age (AUC 0.660, CI 0.541–0.779, p = 0.010). The association between EFS ≥ 6.5 and LOS ≥ 12 days was strengthened with the addition of MoCA < 24 (AUC 0.695, CI 0.584–0.806, p = 0.002). Appendix 11 shows the predictive ability of models examining longer LOS (≥12 days) when EFS ≥ 6.5 and MoCA<24 are added. All analyses were age adjusted.

4. Discussion

This prospective observational study of patients aged over 60 years admitted for arterial vascular surgery showed that this

Table 3
Baseline preoperative variables associated with EFS ≥6.5 (univariate associations).

Baseline characteristics	Frailty		p value
	EFS <6.5 n = 60 (48.0%)	EFS ≥6.5 n = 65 (52.0%)	
Age over 75 years	31 (51.7%)	38 (58.5%)	0.445
Gender (male)	46 (76.7%)	40 (61.5%)	0.068
Marital status (married)	37 (62.7%)	27 (42.9%)	**0.028**
Smoking status (ever smoked)	48 (82.8%)	55 (85.9%)	0.629
Had ≤10 years full time education	32 (55.2%)	39 (60.9%)	0.519
Admitted to hospital in last 12 months	27 (45.0%)	44 (67.7%)	**0.011**
Has homecare	11 (18.3%)	41 (63.1%)	**0.000**
Lives alone	17 (28.3%)	31 (47.7%)	**0.026**
Elective presentation	43 (71.7%)	27 (41.5%)	**0.001**
On 6+ medications	29 (48.3%)	53 (82.8%)	**0.000**
IHD	21 (35.0%)	30 (46.2%)	0.205
Heart failure	3 (5.0%)	11 (16.9%)	**0.047**
AF	10 (16.7%)	20 (30.8%)	0.065
Hypertension	49 (81.7%)	50 (78.1%)	0.623
Chronic lung disease	16 (26.7%)	21 (32.3%)	0.490
Diabetes	11 (18.3%)	20 (30.8%)	0.108
CKD stage 3a or worse	24 (40.0%)	28 (43.1%)	0.727
CVD (prev stroke or TIA)	8 (13.3%)	19 (29.2%)	**0.031**
Multisite vascular disease	19 (31.7%)	30 (46.9%)	0.083
Cancer	12 (20.0%)	11 (16.9%)	0.657
Dementia/cognitive issues	1 (1.7%)	10 (15.4%)	**0.009**
History of depression	6 (10.0%)	14 (21.5%)	0.079
Fall in last 6 months	9 (15.0%)	27 (41.5%)	**0.001**
Visual impairment (visually impaired or blind)	57 (95.0%)	62 (95.4%)	0.920
Hearing impairment	9 (15.3%)	19 (29.2%)	0.063
Urinary incontinence	9 (15.0%)	17 (26.2%)	0.125
Faecal incontinence	5 (8.3%)	7 (10.8%)	0.644
Self reported weight loss	21 (36.2%)	39 (61.9%)	**0.005**
Self-reported exhaustion	17 (28.3%)	27 (41.5%)	0.122
Preoperative grip strength (below age/gender matched norms)	22 (43.1%)	36 (64.3%)	**0.028**
Gait speed <0.6 m/s (preoperatively)	7 (15.2%)	31 (81.6%)	**0.000**
Gait speed <0.8 m/s (preoperatively)	20 (43.5%)	34 (89.5%)	**0.000**
Timed up and go 20 + seconds (preoperatively)	6 (13.0%)	28 (73.7%)	**0.000**
HADS Anxiety score 8+	8 (15.1%)	19 (33.9%)	**0.023**
HADS Depression score 8+	4 (7.5%)	28 (50.0%)	**0.000**
Preoperatively anaemic (Hb < 13 g/dL men and 12 g/dL women)	35 (58.3%)	49 (75.4%)	**0.042**
MoCA <24	26 (45.6%)	51 (91.1%)	**0.000**

Bold type indicates statistically significant values at the 5% level.

Table 4
Postoperative outcomes associated with EFS ≥6.5 (univariate associations).

Postoperative outcomes	Functional status		p value
	EFS <6.5 n = 60 (48.0%)	EFS ≥6.5 n = 65 (52.0%)	
Postoperative delirium	9 (15.0%)	15 (23.1%)	0.252
Pneumonia	2 (3.3%)	8 (12.3%)	0.098
Acute coronary syndrome	2 (3.3%)	8 (12.3%)	0.098
Arrhythmia	3 (5.0%)	7 (10.8%)	0.327
Heart failure	0 (0%)	3 (4.6%)	0.245
Urinary tract infection	2 (3.3%)	4 (6.2%)	0.681
Wound infection	3 (5.1%)	12 (18.5%)	**0.028**
Catheter without indication	5 (8.3%)	10 (15.4%)	0.226
Urinary retention	3 (5.0%)	3 (4.6%)	1.000
Constipation	7 (11.7%)	3 (4.6%)	0.193
Faecal incontinence	3 (5.0%)	15 (23.1%)	**0.005**
Composite post op bowel bladder complications	14 (23.3%)	20 (30.8%)	0.351
Composite post op infective complications	7 (11.9%)	21 (32.3%)	**0.001**
Fall on ward	2 (3.3%)	10 (15.4%)	**0.032**
Dependent transfers at 3 days postoperatively	12 (22.2%)	29 (47.5%)	**0.005**
Discharge TUAG ≥20 s	16 (34.8%)	28 (70.0%)	**0.001 (39 missing)**
Discharge gait speed <0.6 m/s	16 (34.8%)	34 (87.2%)	**0.000 (40 missing)**
Length of stay ≥12days	10 (16.7%)	24 (36.9%)	**0.011**
Length of stay ≥7.5days	22 (36.7%)	40 (61.5%)	**0.005**
Composite postoperative complications	18 (30.5%)	33 (50.8%)	**0.022**
Composite measure adverse functional outcomes	19 (31.7%)	35 (53.8%)	**0.012**

Bold type indicates statistically significant values at the 5% level.

Table 5
Postoperative outcomes associated with EFS ≥6.5 adjusted for significant baseline associations and age.

Postoperative outcomes associated with EFS≥6.5 adjusted for significant baseline associations	Adjusted OR	CI	p value
Age >75 years	0.550	0.190–1.593	0.271
Preoperative care	**7.768**	**2.548–23.681**	**0.000**
Medication 6+	**3.499**	**1.138–10.752**	**0.029**
MoCA <24	**10.179**	**2.770–37.406**	**0.000**
Composite measure of postoperative complications	0.987	0.309–3.158	0.983
Composite measure adverse functional outcomes	1.692	0.511–5.608	0.389
LOS ≥12 days	0.988	0.252–3.871	0.986

Bold type indicates statistically significant values at the 5% level.

population is frail (52% had an EFS score of ≥6.5) and has impaired functional status (60% had TUG >15 s, 45% had gait velocity of <0.6 m/s). Frailty was univariately associated with adverse postoperative outcomes (wound infection, composite measures of postoperative infections, postoperative complications, adverse function outcomes and postoperative faecal incontinence) and was predictive of longer LOS (≥12 days).

A considerable proportion of the patients in this study demonstrated high levels of frailty [mean EFS score was 6.6 (SD 3.05, range 0–14)]. A recent study of 125 patients aged over 70 years having predominantly elective orthopaedic surgery showed a mean EFS score of 4.4 (SD 2.5, range 0–11) [14] in contrast to 120 older patients seen in a geriatric medical clinic in whom the mean EFS score was 7.6 (SD 3.0, range 0–16) [19]. This suggests that arterial vascular surgical patients are comparable to patients needing specialist geriatric medical services. In this study the EFS was dichotomised at the mean value within this study population of 6.5. The original description of the EFS did not validate a cut off level although other work using the tool in older surgical populations has trichotomised the score as high (>7), intermediate [4–7] or low (<4) with observed association with adverse postoperative outcome but no validation data of the cut-off values for this purpose [14].

A similar picture was seen in the functional measures (mean TUG [22.2 s (SD 18.18)] and gait velocity [0.68 m/s (SD 0.31)] were notably slow) though the limitations of these tools in arterial vascular patients needs to be acknowledged. For this reason we also measured hand grip strength with 54% of study participants showing a preoperative grip strength of less than would be expected for their age and gender. There is an association between weaker grip strength and adverse postoperative outcomes in terms of complications and longer LOS [31]. Lower hand grip strength is independently associated with in hospital mortality in patients ventilated on ICU [32].

Slow preoperative TUG is associated with increased postoperative complications and one year mortality following elective colorectal and cardiac surgery [13]. This prospective study of 272 patients aged 65+ showed that 22% had a 'slow' TUG of ≥15 s compared to 60% (50/84) of arterial vascular surgical patients in this study. Similarly, literature in older adults shows that a gait velocity of <0.6 m/s is associated with dependency and increased likelihood of hospitalisation [28]. In patients undergoing cardiac surgery slower preoperative gait velocity was independently associated with a composite end point of in-hospital postoperative mortality and major morbidity [27]. In the current study of arterial vascular surgical patients the mean gait velocity was 0.68 m/s (SD 0.31) and 45% of participants had a gait velocity <0.6 m/s.

Clinically the potential benefits of routinely identifying preoperative frailty and functional limitation include:

[1] Better risk stratification enabling a fuller shared decision making process between patients, relatives and health professionals including making the decision not to operate where appropriate.
[2] Potential modification of risk relating to frailty employing multidisciplinary intervention to improve outcome. Such interventions may include nutritional input [33], exercise intervention [34,35] or functional interventions.
[3] Proactive discharge planning involving prediction of functional deterioration and care needs at discharge [36].

The findings and clinical implications of this study raise several issues for the research agenda in this field. Observational work is needed to more accurately describe the longer term implications of frailty and hospital acquired deconditioning in older vascular surgical patients. Adequately powered studies should examine the impact on postoperative outcomes of interventions to modify frailty and vascular risk factors. Such information could be used to define how geriatric medicine services could optimally be embedded within arterial vascular and other surgical speciality pathways to improve outcome.

4.1. Limitations of the study

Patients with peripheral vascular disease are known to have a slower than average gait velocity [26]. Furthermore 'walking based tests' were not feasible in 45% of patients in this study because of acute illness, critical limb ischaemia or pre-existing mobility issues. There may be value to validating the frailty measures used in this study within the vascular surgical population which was beyond the scope of this work but may be useful in the future. Exclusion of potential participants admitted and discharged over the weekend introduced potential sampling bias, though numbers were small. As expected LOS was positively skewed.

5. Conclusions

Frailty can be measured preoperatively in a mixed cohort of elective and emergency arterial vascular surgical patients using the Edmonton Frail Scale. A considerable proportion of this patient group show a significant level of frailty. Functional measures are less feasible but may have use in selected patient groups such as those undergoing elective procedures. Frailty was associated with baseline cognitive impairment and these were both associated with longer LOS.

Identification of frailty has a potential role in promoting enhanced perioperative risk stratification, risk modification and the timely involvement of geriatric medical teams to reduce adverse postoperative outcomes and LOS. Future research should focus on defining potential interventions to improve outcome for frail arterial vascular surgical patients.

Conflict of interest

None.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ijsu.2015.04.037.

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4.3 Conclusions

As anticipated through the preliminary literature review reported in 1.1 there was a high frequency of previously undiagnosed cognitive impairment and frailty in an unselected older vascular surgical population presenting for elective and emergency surgery. The combination of these geriatric syndromes was associated with a longer length of stay in older vascular surgical patients. Coupled with the multimorbidity in this patient population the role for a multicomponent intervention such as CGA and optimisation in potentially modifying the adverse outcomes contributing to a longer length of stay appears theoretically attractive. The process of developing the CGA intervention, tailoring this to the preoperative setting and evaluating it is described in chapter 5.

Chapter 5 - Evaluating a complex intervention; randomised clinical study

5.0 Introduction

According to the MRC framework for 'Developing and evaluating complex interventions' the following stages have been undertaken and presented in this thesis. Identifying or developing appropriate theory involved systematically reviewing the literature on CGA and optimisation methodology in the preoperative setting and performing a narrative synthesis of the available evidence. In modelling process and outcomes, the extent to which geriatrician led CGA and optimisation based services for older surgical patients already existed in NHS trusts was examined using an electronic survey conducted nationally. Involving all clinical and patient stakeholders resulted in a co-designed observational study which showed that older vascular surgical patients are often frail with cognitive impairment and that the combination of these preoperative factors is associated with a longer length of hospital stay. Having scoped and defined the issues and potential intervention using observational research and patient and public co-design, a single site randomised controlled trial design was chosen in order to evaluate the impact of the complex multicomponent intervention of CGA and optimisation on the primary end point of hospital length of stay.

This study aim was; to examine whether preoperative CGA and optimisation reduces length of stay in older patients undergoing vascular surgery compared to standard preoperative assessment processes.

5.1 Methods – evaluation of multicomponent intervention

The study methods are described in the paper presented in section 5.2. This methods section describes the processes used to refine the methods used in the final study design. This involved consideration of the following;

Ethics

Ethical approval for this study was granted (12/LO/0655)

Refining the intervention through stakeholder co-design

The next stage of this programme of work was to develop the CGA and optimisation intervention, tailor it to the preoperative setting and design the evaluation study. According to MRC guidance undertaking a randomised clinical trial would be the preferred study design if possible. The wide stakeholder group, approached during the co-design of the observational study (chapter 4), was recontacted. This group included patients and their relatives or carers, vascular surgeons and nurses, vascular anaesthetists and critical care teams, preoperative clinic nurses, organ specific physicians, physiotherapists, occupational therapists and managers in all relevant clinical areas. As before different approaches were used to engage different groups.

Patient and carer stakeholders

A small convenience sample of patients who had undergone vascular surgery, and their families, were approached and asked to participate in small group sessions with the researcher. Travel costs were reimbursed and refreshments provided. During these meetings, the potential CGA intervention was explained and the possible study designs

(including randomisation) and study outcomes were discussed. The existing preoperative assessment process for both elective and emergency patients was mapped using electronic notes review and discussion with patients who had recently been through the pathway of surgical care. This allowed participants to gain a detailed understanding of the care to be received by the control group (usual care) as compared to the care planned for the intervention group (CGA), if a randomised controlled trial was to be undertaken.

The process of care measure, length of hospital stay, used in the observational study (chapter 4), has also been used before in perioperative CGA studies due to its impact on financial cost saving and was therefore a potentially attractive primary outcome measure to clinicians and hospital managers. However, as with the observational study, it also proved to be important to patients and their families who all reported that minimising time in hospital was paramount. In addition, patients suggested excluding the emergency patient group in the initial intervention study as they felt this would enhance the chance of success by focusing on elective patients in whom there would be adequate time to medically optimise with CGA prior to surgery.

Patient and public co-design of study practicalities was key. It is usual in research in non-emergency conditions to approach potential study participants, provide study details verbally and in writing before allowing a 'cooling off' period during which the potential participant can consider the study. Following this period, the study team then make contact again and if the participant is willing to enrol in the study the process of written consent is undertaken or scheduled. However, an innovative

approach to consent and randomisation was undertaken in this 'non-emergency' study due to co-design with patients. All older patients involved in the PPI process voiced a dislike of multiple phone conversations and attendances at the hospital. Given the low level of perceived risk in the study, all patients advocated a process of approaching potential study participants, providing written information, allowing sufficient time to read this and ask questions before consenting to participation and undergoing randomisation (to intervention arm or standard care arm) in one meeting. The patient and consultee information sheets and consent forms can be seen in appendices 9-12.

Clinical stakeholders

Nursing stakeholders from both the inpatient and outpatient setting were concerned that the CGA screening tools used to identify multidomain issues including cognitive assessments, measurement of frailty, and scores of functional status would be too onerous for the older patient group in the context of potential anxiety in the preoperative period. The patient stakeholder group piloted the proposed tools in order to describe how long it would take to complete them and to obtain their feedback on the process. Based on this together with the feasibility work using MoCA and EFS described in chapter 4, the tools to be used in the CGA based study intervention were refined and the nursing staff remained engaged in the research process. Vascular surgeons were again engaged at the monthly audit meeting where the results of the work presented in chapters 2-4 was presented. The proposed study interventions were discussed and possible study designs outlined. A single site randomised controlled trial adhered most closely to the MRC guidelines but raised feasibility issues. Specifically, vascular surgical stakeholders expressed concerns regarding recruitment rates as the

presumption was that patients would be reluctant to accept randomisation to standard pre-assessment or the preoperative CGA interventions. In addition, anaesthetists, who together with preoperative clinic assessment nurses, deliver the standard preoperative assessment within the potential study centre expressed concern about numerous issues being identified at CGA resulting in multiple ongoing referrals to different physicians delaying the surgical pathway. This opened discussion about the single point of CGA delivery supported by the academic literature and involved further engagement with patients and the public who felt that randomisation would be acceptable to potential participants.

Following this process and having scoped and defined the issues and potential intervention, a single site randomised controlled trial design was chosen to examine;
- whether preoperative CGA and optimisation reduces length of stay in older patients undergoing vascular surgery compared to standard preoperative assessment processes
- whether preoperative CGA and optimisation reduces postoperative medical complications in older patients undergoing vascular surgery compared to standard preoperative assessment processes

Aiming to make the CGA and optimisation intervention transparent and therefore translatable

The final step of the MRC framework involves translation of the studied intervention to a wider patient population if benefit is proved in the evaluation phase. Therefore, in order to enable subsequent dissemination with fidelity the CGA and optimisation intervention was protocolised as much as was possible. Clinical issues identified

through the observational study (chapter 4) prompted the design of local guidelines for investigation and management where no national guidance already existed. For example, these included a protocol for the investigation and management of exertional cardiac chest pain identified at preoperative assessment, a guideline to manage anaemia and a protocol to minimise the potential impact of delirium or frailty by adapting the literature reviewed in 1.3 and 1.4 to the preoperative setting (appendices 13-16).

Aiming to better understand the impact of the 'black box' of the multicomponent CGA and optimisation intervention

With the aim of promoting translation of the intervention, the secondary outcomes measures were chosen to illustrate how any improvement seen in the primary outcome, length of stay, was achieved through the process of CGA and optimisation. To this end postoperative medical complications and issues with discharge planning were felt to be useful measures to describe how the intervention may effect change. Combining these outcomes measures with the standardised intervention may allow easier translation to other centres keen to examine the impact of preoperative CGA or establish clinical services providing such an intervention.

Inclusion of patients who lacked capacity to consent to study participation

According to sections 30-34 of the Mental Capacity Act (2005) ethical approval was sought and granted to recruit patient participants who lacked capacity to consent. In these cases, a consultee was approached and asked to provide written assent on behalf of the participant. This approach was taken in order that bias, due to exclusion

of those with cognitive impairment or dementia resulting in a lack of capacity to consent to study participation, was minimised, and that those with potentially more to be gained through the CGA approach were included.

Limitations

A single site randomised trial is at significant risk of bias. Such bias would primarily occur through contamination of the control group through observation of the CGA intervention in a single site. As described attempts to minimise this acknowledged limitation were made by conducting the intervention and control clinics in different locations with separate staff groups. Whilst contamination may have occurred due to staff interaction the study showed a clear difference between the two groups suggesting that if bias did occur it was not likely to have been of significant magnitude. In addition, complete blinding was impossible increasing the risk of bias. However, the use of length of stay as the primary outcome measure minimised this bias as this variable is routinely collected by hospital staff unaware of the study and recorded on electronic hospital systems preventing research staff needing to interpret data.

5.2 Results

Contribution of each co-author to publication

Judith Partridge, Danielle Harari, Finbarr Martin and Jugdeep Dhesi all made substantial contribution to conception and design of the study. Judith Partridge and Aminata Mohammed acquired data with analysis performed by Judith Partridge, Danielle Harari, Jugdeep Dhesi and Janet Peacock. Judith Partridge and Jugdeep Dhesi

wrote the manuscript with intellectual revision from Danielle Harari, Janet Peacock, Rachel Bell and Finbarr Martin.

Randomized clinical trial

Randomized clinical trial of comprehensive geriatric assessment and optimization in vascular surgery

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Background: **Increasing numbers of older patients are undergoing vascular surgery. Inadequate preoperative assessment and optimization may contribute to increased postoperative morbidity and mortality.**

Methods: **Patients aged at least 65 years scheduled for elective aortic aneurysm repair or lower-limb arterial surgery were enrolled in an RCT of standard preoperative assessment or preoperative comprehensive geriatric assessment and optimization. Randomization was stratified by sex and surgical site (aorta/lower limb). Primary outcome was length of hospital stay. Secondary outcome measures included new medical co-morbidities, postoperative medical or surgical complications, discharge to a higher level of dependency and 30-day readmission rate.**

Results: **A total of 176 patients were included in the final analysis (control 91, intervention 85). Geometric mean length of stay was 5·53 days in the control group and 3·32 days in the intervention group (ratio of geometric means 0·60, 95 per cent c.i. 0·46 to 0·79; $P < 0·001$). There was a lower incidence of delirium (11 *versus* 24 per cent; $P = 0·018$), cardiac complications (8 *versus* 27 per cent; $P = 0·001$) and bladder/bowel complications (33 *versus* 55 per cent; $P = 0·003$) in the intervention group compared with the control group. Patients in the intervention group were less likely to require discharge to a higher level of dependency (4 of 85 *versus* 12 of 91; $P = 0·051$).**

Conclusion: **In this study of patients aged 65 years or older undergoing vascular surgery, preoperative comprehensive geriatric assessment was associated with a shorter length of hospital stay. Patients undergoing assessment and optimization had a lower incidence of complications and were less likely to be discharged to a higher level of dependency. Registration number: ISRCTN23142588 (http://www.controlled-trials.com).**

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Introduction

As the population ages the number of older people undergoing surgical procedures is increasing[1]. Despite improved mortality and symptomatic benefits of surgery for older people[2–4], there continues to be an excess of adverse postoperative outcomes in older patients[5–9]. This is likely to be explained by a combination of physiological changes, the cumulative effect of multiple morbidities and the presence of geriatric syndromes. Observational work within the older vascular surgical population has identified a significant burden of undiagnosed cognitive impairment, high incidence of delirium, considerable frailty and impaired functional status[10,11]. Vascular risk factors such as smoking, hypertension and hypercholesterolaemia, which are common in patients undergoing vascular surgery, are also independent risk factors for cognitive impairment, postoperative delirium and frailty[12–15]. Furthermore, vascular risk factors increase the risk of postoperative morbidity. Such postoperative complications can contribute to increased mortality, poorer patient experience, prolonged hospital stay and greater financial costs[16,17].

Evidence is emerging to suggest that systematic structured preoperative assessment and clinical optimization of older surgical patients may improve postoperative outcomes[18,19]. Comprehensive geriatric assessment is an established and evidence-based method of evaluating and optimizing physical, psychological, functional and

social issues in older patients[20,21]. The initial assessment prompts the development of an individualized care plan that includes investigation, treatment, rehabilitation support and long-term follow-up. For example, a patient may receive medical optimization of heart failure, assessment and management of newly identified cognitive impairment, and provision of mobility aids or referral to therapy-based exercise programmes. The use of comprehensive geriatric assessment in medical inpatients and community-dwelling older people has been shown to improve mortality at 36-month follow-up, to increase the chance of living independently at home, and to confer a positive effect on physical and cognitive function[20]. A recent Cochrane review and meta-analysis[21] of 22 trials showed that patients who underwent comprehensive geriatric assessment in acute geriatric wards were more likely to be alive and in their own homes at 12 months than patients receiving general medical care. Furthermore, fewer patients were institutionalized at hospital discharge and cognitive decline was less pronounced in the group that received comprehensive geriatric assessment.

Despite the evidence supporting the use of comprehensive geriatric assessment in the medical setting, this process remains relatively understudied in the surgical population. Where comprehensive geriatric assessment differs from other preoperative risk assessment tools is in the individualized multidomain optimization that is prompted by the assessment process. It is this optimization that will potentially modify perioperative risk and improve postoperative outcomes. A systematic review and narrative synthesis[19] concluded that preoperative comprehensive geriatric assessment is likely to have a positive impact on postoperative outcomes in older patients undergoing elective surgery, but recommended further research to investigate the optimal approaches and its effectiveness in this setting.

Methods

A single-centre RCT was performed within an inner-city teaching hospital with a tertiary referral practice for vascular arterial surgery (ISRCTN23142588, UKCRN 13260). Eligible and consenting patients were randomized to receive either comprehensive geriatric assessment and optimization, or usual care. Ethical approval was given by South East London Research Ethics Committee (12/LO/0655). Eligibility criteria were patients aged at least 65 years scheduled for elective endovascular/open aortic aneurysm repair or lower-limb arterial bypass surgery. Patients were not eligible if they were admitted directly to the ward from the surgical clinic or emergency department for emergency or very urgent surgery, which precluded the opportunity for outpatient preoperative assessment and optimization.

Patients and carers were involved in the design of this study, including the initial development of the research question. Participants from an observational study that preceded this trial advised on recruitment, randomization and follow-up. This involved discussion about the burden of the intervention, which was felt to be minimal by the patients consulted. All study participants will be offered a written summary of the study results.

Recruitment, consent and randomization

Patients were approached by a research nurse or fellow in the vascular surgery outpatient clinic once listed for surgery. Those satisfying the inclusion criteria were assessed for capacity to consent to study participation. Patients lacking capacity to consent were recruited under sections 30–34 of the Mental Capacity Act[22]. Written consent was obtained (from either patients or consultees). Patients were approached, assessed for eligibility and consented at the first meeting after they had read the patient information sheet.

Randomization was internet-based and was carried out independently by the King's Clinical Trials Unit (www.ctu.co.uk) using a 1 : 1 allocation, and stratified according to sex and site of surgical procedure (aorta, lower limb). According to randomized group allocation, participants were given appointments to attend either a standard preassessment clinic (routine care within the hospital) or the study intervention, a comprehensive geriatric assessment and optimization clinic.

Clinical care

Intervention group

Patients in the intervention group received comprehensive geriatric assessment and optimization in an outpatient clinic setting. A geographically separate clinic on a different hospital site with entirely different clinic staff was used to minimize contamination bias between the two groups in the single centre. Patients were assessed and optimized according to peer-reviewed protocols based on current evidence, national and hospital guidelines, and expert opinion (examples can be found in *Figs S1–S3* and *Tables S1* and *S2*, supporting information). Comprehensive geriatric assessment was delivered by a multidisciplinary team (geriatrician, clinical nurse specialist, social worker, occupational therapist) according to individual patient

need. The intervention was documented in an individualized care plan available to all healthcare professionals on the electronic patient record. This care plan provided advice regarding the prevention and management of anticipated postoperative complications, but did not refer to the patient's involvement in the study.

Control group

The control group received standard preoperative care. Within the participating centre, this consisted of a nurse-led preoperative assessment clinic where a protocolized appraisal of anaesthetic and medical issues was conducted. This process tended to focus on the binary labelling of 'fit' or 'unfit' for anaesthesia/surgery, and was not designed to optimize patients' fitness. If issues that might affect surgery were identified, a more detailed specialist medical or anaesthetic evaluation was requested, or patients were referred back to their general practitioner.

Postoperative care

In both groups, postoperative care was delivered by surgical teams who were unaware of the patient's involvement in the study. This routine care involved junior surgical staff and clinical nurse specialists utilizing all electronic clinical documents (including the individualized care plans generated following comprehensive geriatric assessment in the intervention group).

Outcome measures

The primary outcome measure was duration of hospital stay; this was recorded routinely by hospital administrative staff who were unaware of the study, and extracted from the hospital electronic patient record by an unblinded research nurse. Use of length of stay as the primary outcome measure was based on *a priori* consultation with patients and carers, as it was considered to encapsulate both the overall 'success' of the hospital stay and the patient experience. It is also a major determinant of hospital costs per episode of care.

Secondary outcome measures were: new co-morbid diagnoses made, such as cognitive impairment (yes/no); postoperative medical and surgical complications, including delirium (yes/no); discharge to a higher level of care dependency (new care package or reablement at discharge, discharge to rehabilitation facility or other hospital, and new care home placement); and readmission to hospital within 30 days. These were recorded by an unblinded research nurse using predefined criteria for the presence or absence of complications according to the clinical record, medication record and results of investigations. Data were taken from the clinical records made by usual care teams that were unaware of the study.

To explore potential clinical explanations for any difference observed in length of stay, all new diagnoses, investigations, discussions, referrals and medication changes made at preoperative assessments were recorded as secondary outcomes.

Statistical analysis

Mean(s.d.) length of hospital stay in the control group was expected to be 6·5(4·0) days, based on previous routine activity data in this surgical unit. A reduction of 25 per cent (1·6 days) was judged to be clinically and financially important. Assuming 80 per cent power and a two-sided significance level of 5 per cent, a total sample size of 198 patients was required (99 per group). Attrition rates were expected to be negligible from previous observational work that showed no drop-outs[10]; the target sample size was inflated (by 5 per cent) to 208.

Baseline data are presented as mean(s.d.) (continuous data), or frequencies and percentages (categorical data). The primary analysis was by intention to treat. The primary outcome, length of hospital stay, was positively skewed and so was log-transformed for analysis, and then back-transformed to give the ratio of geometric means with a 95 per cent c.i. This provided an estimate of the relative change in length of stay in the intervention group compared with the control group. The difference in outcome between the two randomized groups was analysed using multiple regression that included the stratification factors sex and surgical site as co-variables. Where there was an observed imbalance in baseline variables, a sensitivity analysis was performed to adjust the primary outcome analysis for these factors and test the robustness of the findings.

Binary outcomes were compared by allocated group using the χ^2 test (or Fisher's exact test where the frequencies were small). Wherever possible, all differences between the trial arms are given with 95 per cent confidence intervals, calculated using Wilson's method in Confidence Interval Analysis (CIA) software (www.som.soton.ac.uk/cia/). It was not possible to adjust for the stratification factors using logistic regression for the majority of secondary outcomes owing to small numbers of events.

The analysis was conducted unblinded by a biostatistician who had contributed to the protocol and plan of analysis, but was not part of the clinical trial team.

Results

A total of 209 patients were recruited between November 2012 and February 2014, of whom 105 were assigned

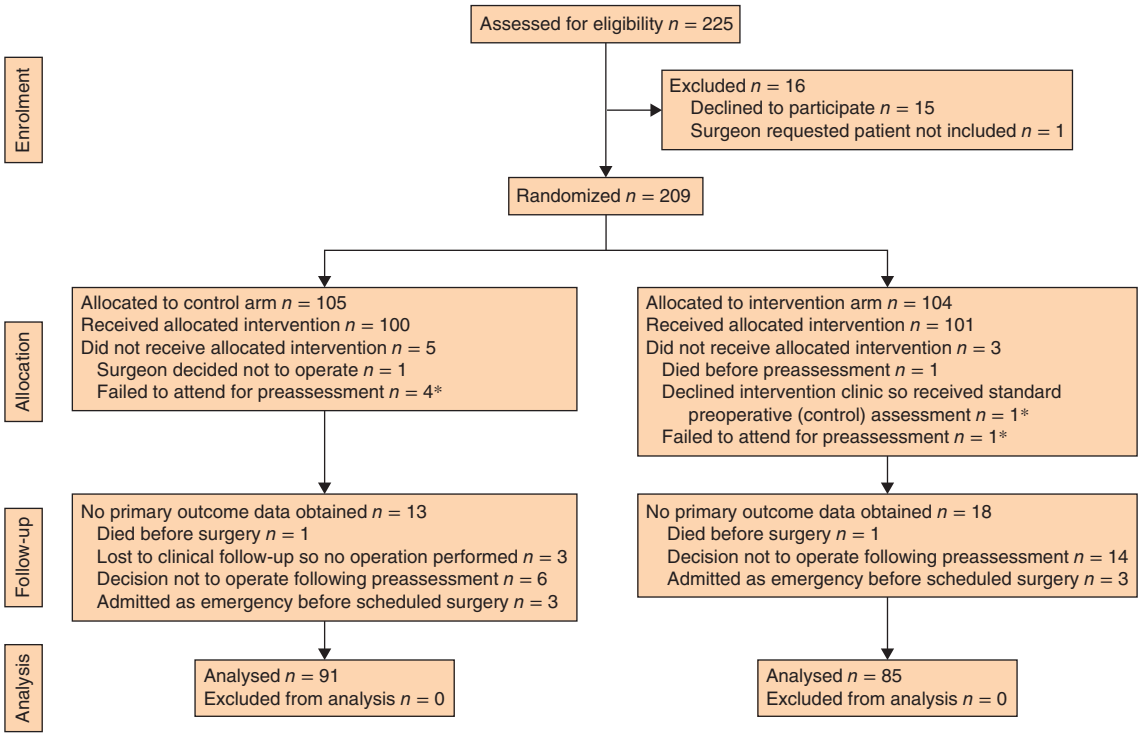

Fig. 1 CONSORT diagram for the trial. *Included in accordance with intention-to-treat analysis

randomly to the control arm and 104 to the intervention arm (*Fig. 1*). No patient withdrew consent to participate in the study and none was lost to follow-up. The primary outcome (length of hospital stay in days) was available for 176 patients (91 control, 85 intervention) (*Fig. 1*).

Baseline characteristics

There were some differences between the randomized groups in terms of baseline characteristics (*Table 1*).

Primary outcome

Mean length of stay in the intervention group was reduced by 40 per cent compared with that in the control group (ratio of geometric means 0·60, 95 per cent c.i. 0·46 to 0·79; $P < 0·001$). This reduction equated to a mean reduction of just over 2 days (*Table 2*). The difference was virtually unchanged after adjusting for the observed baseline imbalance in history of cerebrovascular disease, falls and smoking (ratio of geometric means 0·62, 0·46 to 0·83; $P = 0·002$).

Secondary outcomes

There were significantly lower proportions of patients with postoperative delirium, cardiac complications and

Table 1 Baseline variables in control and intervention groups

	Control ($n = 105$)	Intervention ($n = 104$)
Age (years)*	75·5(6·3)	75·5(6·6)
Sex ratio (M : F)	79 : 26	80 : 24
Current or ex-smoker	68 of 89 (76)	94 of 102 (92·2)
Alcohol consumption (units/week)*	6·6(14·1)	10·3(17·5)
Ischaemic heart disease	37 of 100 (37·0)	39 (37·5)
Cardiac failure	6 (5·7)	8 (7·7)
Atrial fibrillation	17 of 100 (17·0)	15 of 100 (15·0)
COPD	25 of 100 (25·0)	25 of 100 (25·0)
Diabetes	25 of 100 (25·0)	26 of 100 (26·0)
Cerebrovascular disease	21 of 100 (21·0)	10 (9·6)
Cancer	15 of 100 (15·0)	17 of 100 (17·0)
Hypertension	81 of 101 (80·2)	78 of 101 (77·2)
Dementia	5 (4·8)	2 (1·9)
Falls	10 (9·5)	26 of 100 (26·0)
Peripheral artery disease	40 of 100 (40·0)	46 of 102 (45·1)
Multiple-site vascular disease	22 of 100 (22·0)	27 of 100 (27·0)
End-stage renal failure	2 (1·9)	0 (0)
No. of medications*	6·1(3·0)	6·4(3·3)
Haemoglobin (g/l)*	133(17)	129(16)
Creatinine (μmol/l)*	106(54)	101(44)
eGFR (ml/min)*	66(25)	69(26)
Self-reported exercise tolerance†	24 of 73 (33)	38 of 100 (38·0)
Surgical procedure (aortic)	64 (61·0)	64 (61·5)

Values in parentheses are percentages unless indicated otherwise; note that the denominator varies according to missing data (predominantly in the control group). *Values are mean(s.d.). †Unable to manage one flight of stairs. COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate.

Table 2 Primary and secondary outcomes of participants who progressed to surgery, according to allocated study arm

	Control ($n = 91$)	Intervention ($n = 85$)	Difference (intervention – control)‡	P¶¶
Primary outcome				
Length of hospital stay (days)*	5·53	3·32	0·60 (0·46, 0·79)§§	< 0·001##
Secondary outcomes				
Postoperative delirium	22 (24)	9 (11)	−14 (−25, −2)	0·018
Acute coronary syndrome	4 (4)	0 (0)	−4 (−11, 1)	0·051***
Cardiac failure	5 (5)	1 (1)	−4 (−11, 2)	0·212***
Tachyarrhythmia	17 (19)	3 (4)	−15 (−25, −6)	0·002***
Bradyarrhythmia	7 (8)	4 (5)	−3 (−11, 5)	0·413***
Pneumonia	12 (13)	8 (9)	−4 (−13, 6)	0·430
Wound infection	13 (14)	4 (5)	−10 (−19, 0)	0·032***
Urinary tract infection	9 (10)	4 (5)	−5 (14, 3)	0·196***
Constipation	40 (44)	24 (28)	−16 (−29, −2)	0·026
Faecal incontinence	9 (10)	1 (1)	−9 (−17, −2)	0·019***
Catheter issue	7 (8)	4 (5)	−3 (−11, 5)	0·413***
Fall	7 (8)	2 (2)	−5 (−13, 2)	0·171***
Postoperative cardiac complication§	25 (27)	7 (8)	−19 (−30, −8)	0·001
Postoperative pulmonary complication¶	13 (14)	8 (9)	−5 (−15, 5)	0·319
Postoperative infective complication#	25 (27)	14 (16)	−11 (−23, 1)	0·086
Postoperative bowel and bladder complications**	50 (55)	28 (33)	−22 (−35, −7)	0·003
Postoperative vascular surgery-related issues††	10 (11)	6 (7)	−4 (−13, 5)	0·365
Discharge timed get up and go (s)†	20·1(11·6)	18·9(1·8)	−1·2 (−4·7, 2·3)	0·584
Discharge gait speed (m/s)†	0·7(0·2)	0·7(0·3)	0·0 (−0·1, 0·1)	0·696
Postoperative haemoglobin (g/l)†	104(84)	100(21)	−4 (−23, 15)	0·657
Postoperative blood transfusion (units infused)†	1·0(3·7)	0·3(0·7)	−0·7 (−1·5, 0·1)	0·065
Postoperative creatinine (μmol/l)†	134(120)	108(52)	−26 (−54, 2)	0·070
Unplanned 30-day readmission	10 (11)	15 (18)	7 (−4, 17)	0·193
Composite measure of complicated discharge‡‡	12 (13)	4 (5)	9 (−17, 0)	0·051***
Level 2/3 care used immediately after surgery	39 (43)	26 (31)	−12 (−26, 2)	0·082

Values in parentheses are percentages unless indicated otherwise; values are *geometric mean, †mean(s.d.) and ‡values in parentheses are 95 per cent confidence intervals. §Acute coronary syndrome, heart failure, tachyarrhythmia or bradyarrhythmia; ¶pneumonia, infective exacerbation of chronic obstructive pulmonary disease (COPD); #pneumonia, infective exacerbation of COPD, wound infection, urinary tract infection; **urinary tract infection, catheter-related issue, constipation, faecal incontinence; ††bleed, vessel rupture, occlusion, paraplegia; ‡‡new care package, reablement, discharge to bed-based rehabilitation, other hospital, new care home placement. §§Difference expressed as the ratio of geometric means (intervention/control); the analysis was adjusted for stratification factors sex and site of surgery. ¶¶χ^2 test, except ##multiple regression and ***Fisher's exact test.

bladder/bowel issues, with a trend towards fewer infective episodes and fewer units of blood transfused in the intervention compared with the control group (*Table 2*).

Sensitivity analyses for the proportions with delirium were conducted to adjust for differences in potential confounders between the two groups (history of cerebrovascular disease, falls and smoking), but these did not affect the size of difference observed. Furthermore, patients in the intervention group were less likely to have care or rehabilitation needs necessitating a change in discharge destination or new provision of rehabilitation and/or care; but this did not reach statistical significance ($P = 0·051$) (*Fig. 2*).

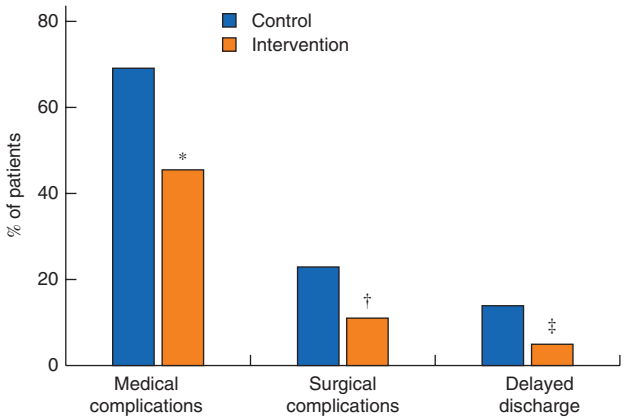

Fig. 2 Percentage of patients with complications and delayed discharge by trial arm. *$P = 0·002$, †$P = 0·042$, ‡$P = 0·051$ *versus* control (χ^2 test)

Assessment and optimization according to comprehensive geriatric assessment

Comprehensive geriatric assessment recognized previously undiagnosed issues across multiple domains. Cognitive

Table 3 Identification of previously unrecognized issues across multiple domains using comprehensive geriatric assessment according to allocated study arm

	Control ($n = 100$)	Intervention ($n = 101$)	P*
Delirium risk assessment undertaken	0 (0)	99 (98·0)	< 0·001
New diagnosis made at preoperative assessment			
Ischaemic heart disease	0 (0)	5 (5·0)	0·059
Cardiac failure	0 (0)	5 (5·0)	0·059
Atrial fibrillation	1 (1·0)	3 (3·0)	0·621
COPD	0 (0)	15 (14·9)	< 0·001
Diabetes	0 (0)	2 (2·0)	0·498
Cerebrovascular disease	0 (0)	1 (1·0)	1·000
Cancer	0 (0)	2 (2·0)	0·498
Cognitive impairment	1 (1·0)	47 (46·5)	< 0·001
Chronic kidney disease (stage ≥ 3)	0 (0)	26 (25·7)	< 0·001
Valve lesion	3 (3·0)	9 (8·9)	0·134
Tachyarrhythmia or bradyarrhythmia	0 (0)	2 (2·0)	0·498
Parkinson's disease	0 (0)	1 (1·0)	1·000
Composite measure of new diagnosis made at preoperative assessment	5 (5·0)	64 (63·4)	< 0·001†

Values in parentheses are percentages. COPD, chronic obstructive pulmonary disease. *Fisher's exact test, except †χ^2 test.

Table 4 Preoperative optimization using short-term and longer-term modifications and planning through comprehensive geriatric assessment according to allocated study arm

	Control ($n = 100$)	Intervention ($n = 101$)	P*
GP informed about cognitive issues	0 (0)	99 (98·0)	< 0·001
Memory clinic referral suggested to GP	0 (0)	54 (53·5)	< 0·001
Discussion with patient and family about cognitive issues	0 (0)	98 (97·0)	< 0·001
Multicomponent optimization to modify delirium risk undertaken	0 (0)	60 (59·4)	< 0·001
Multicomponent optimization to modify risk of functional deterioration undertaken	0 (0)	29 (28·7)	< 0·001
Physiotherapy referral	0 (0)	3 (3·0)	0·246
Occupational therapy referral	0 (0)	26 (25·7)	< 0·001
Social work referral	0 (0)	35 (34·7)	< 0·001
Medications changed before surgery	4 (4·0)	87 (86·1)	< 0·001
Level 2/3 care advised	26 of 90 (29)	25 of 83 (30)	0·902†
Onward referral to other specialty for long-term (non-preoperative) management suggested	1 (1·0)	36 (35·6)	< 0·001
Advice to ward teams given	0 (0)	93 (92·1)	< 0·001
Longer-term GP follow-up suggested	2 (2·0)	85 (84·2)	< 0·001

Values in parentheses are percentages. GP, general practitioner. *Fisher's exact test, except †χ^2 test.

disorders, delirium risk, frailty and medical morbidity were identified more frequently in the intervention group than the control group (*Table 3*). In accordance with the objectives of comprehensive geriatric assessment, the recognition of these issues prompted preoperative management (such as medication changes), longer-term follow-up (for example by primary care), and proactive discussion with patients and families (for example about cognitive issues) (*Table 4*).

Discussion

In this RCT, preoperative comprehensive geriatric assessment was associated with a shorter hospital stay for older patients undergoing elective vascular surgery, with no increase in 30-day readmission rate. The observed reduction in length of stay in those receiving comprehensive geriatric assessment probably resulted from fewer postoperative medical complications, anticipation and modification of potential functional and discharge issues, and streamlining of the patient pathway.

This finding is in keeping with existing literature on comprehensive geriatric assessment in other settings[20,21] where the multidomain assessment and optimization of older patients is thought to improve both physical and cognitive function. In the present study, the recognition of previously undiagnosed pathology facilitated optimization through both medical management (higher

rates of medication change made in intervention group) and multidisciplinary intervention (higher rates of preoperative therapy and social work referral). This prompted standardized management of anticipated postoperative complications through clear communication with ward teams and other health professionals. Furthermore, communication with patients and their families was more commonly undertaken in the intervention arm, allowing anticipation of information regarding risk of postoperative complications such as delirium, expected length of stay and expectations around discharge planning. This fuller preoperative assessment and optimization of medical morbidity, anticipation and mitigation of potential social issues at discharge, and advice on standardized management of postoperative complications are postulated to be responsible for the observed reduction in length of stay.

The number of patients who did not undergo surgery was greater in the intervention arm than in the control arm. The comprehensive assessment undertaken in the intervention group was shown to increase significantly the number of new diagnoses made. These included chronic obstructive pulmonary disease, chronic kidney disease (stage 3 or worse) and cognitive impairment, with a trend towards larger numbers of new diagnoses of ischaemic heart disease and cardiac failure. It is possible that this fuller assessment of perioperative risk resulted in the greater number of decisions to manage patients conservatively in the intervention group. Although the effect of the comprehensive intervention on patient selection may have influenced length of stay, the numbers are such that this would not account for the marked change observed. The impact of comprehensive geriatric assessment on patient selection for surgery in this study has important implications for clinical practice.

There are limitations to the study. The primary outcome measure was documented in the electronic patient record by hospital administrative staff who were unaware of the study. The length of stay was then recorded by an unblinded research nurse, but the objective method of collecting the measure eliminated the risk of bias. Secondary outcomes were recorded by the research nurse using predefined criteria for the presence or absence of complications according to the clinical record, medication records and results of investigations. These data were taken from the clinical records made by usual care teams, including a succession of junior medical staff on rotation who were unaware of the patient's enrolment in the study, making it unlikely that there was a systematic tendency for any difference in their record-keeping. The predefined criteria for the secondary outcomes provided minimal scope for interpretation of their presence or absence by the research nurse.

Randomization ensured a similar distribution of baseline characteristics between the two groups; however, there was a higher rate of previous stroke in the control group, and higher reported rates of previous falls and current smoking in the intervention group. It is possible that these differences could be explained by a fuller assessment in the intervention group, where events reported by patients as strokes were discounted after assessment, and more accurate details on falls and smoking were obtained. Whether or not these findings were true differences or reporting differences, adjustment using sensitivity analysis showed no impact on the observed difference in length of stay between the two groups.

There is potential contamination between the groups as the study was conducted within a single surgical service in one hospital trust. Steps undertaken to minimize this bias included the use of clinics in different geographical locations employing different staff for preoperative care in each trial arm, ensuring that staff from one clinic could not directly observe actions taken in the other clinic. Any contamination that did occur would have been expected to reduce differences in outcomes.

The results of this study have potential significance for other centres offering elective vascular surgery to older patients. Although patients in the present study were undergoing vascular surgery, the findings build on literature examining similar multicomponent interventions in other older surgical populations, such as those following hip fracture[23] or undergoing elective orthopaedic surgery[24]. Such significant findings suggest that the application of preoperative comprehensive geriatric assessment may be relevant to older patients undergoing elective and emergency surgery across other surgical subspecialties, including cancer surgery.

Future work in this area could include economic evaluation of the intervention, better understanding of the mechanisms underlying the observed improvement in length of stay and larger-scale evaluation of the intervention. The translation of study findings into routine clinical practice should be further explored using implementation science.

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Supporting information

Additional supporting information may be found in the online version of this article:

Fig. S1 Cognition protocol (Word document)

Fig. S2 Anaemia protocol (Word document)

Fig. S3 Cardiac evaluation (Word document)

Table S1 Frailty domains (Word document)

Table S2 Stepwise approach to antiplatelet management for complex aneurysm repair (Word document)

5.3 Conclusions

This single site randomised controlled trial has shown that preoperative CGA and optimisation reduces length of hospital stay in older patients undergoing elective aortic and lower limb arterial surgery when compared with standard preoperative assessment. The observed reduction in length of stay of 40% is likely due to fewer medical complications and a trend towards fewer delayed discharges. A discussion of these study findings in the wider context of more recently published research papers and the national perioperative medicine agenda will be provided in chapter 7. In addition, the next step of the MRC framework will be considered with a focus on how this research programme should be furthered to ensure that the observed findings from this thesis are translated more widely.

Chapter 6 - Experience of postoperative delirium

6.0 Introduction

As described in chapter 4 and 5, throughout this research programme patients, their relatives and carers have been involved in co-design and co-production of the research questions and execution of the resulting studies. During this process several patients and relatives voiced their concern regarding emotional distress and a lack of understanding regarding their experience of delirium. As described in chapter 1.3, delirium is defined by the DSM 5 criteria as a condition of acute onset and usually fluctuating course characterised by a disturbance in attention and awareness and cognition attributable to an underlying cause and not solely due to coma. Postoperative delirium is frequently observed in those undergoing vascular surgery. Whilst evidence supports the use of multicomponent interventions to reduce the incidence of delirium, as observed in the randomised controlled study described in chapter 5, even if rates are reduced it will continue to be a significant burden for those undergoing vascular surgery. The awareness of this issue raised by patients and relatives promoted a literature review presented in 6.1 and the development and execution of a further observational study to explore this issue in greater depth. The findings of this final study are presented in 6.3.

6.1 Literature review

Contribution of each co-author to publication

All authors conceived the paper with Judith Partridge reviewing the literature and drafting the manuscript. Danielle Harari, Jugdeep Dhesi and Finbarr Martin critically edited the manuscript.

REVIEW ARTICLE

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The delirium experience: what is the effect on patients, relatives and staff and what can be done to modify this?

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Background: Delirium is a common clinical syndrome with significant associated mortality, morbidity and financial cost. Less is understood about the experience of delirium for the patient, their family and staff involved in their care.

Objective: This synthesis draws on qualitative and quantitative literature examining different populations (patients, relatives and staff) in different clinical settings (intensive care units, surgery and hospice care) to provide a clinical summary of the delirium experience from the perspective of patients, relatives and staff.

Design: A literature search was conducted in Ovid, MEDLINE, Embase, PsychINFO, British Nursing Index and Archive and PubMed between 1980 and 2011 using the terms 'delirium' combined with 'distress', 'recall', 'anxiety', 'depression', 'PTSD', 'experience' and 'patient education'. Articles were restricted to English language only.

Results: Evidence suggests that some patients recall delirium and that recollections are generally distressing. Distress may be greater in relatives witnessing delirium and is also reported in professional staff. This distress may result in longer-term psychological sequelae. Remedial action, such as explanatory information to patients and their families, may reduce distress and psychological morbidity.

Conclusions: A better understanding of the experience and psychological consequences of delirium will inform the development of appropriate methods of providing support and information to those at risk of delirium and their families or carers. Copyright © 2012 John Wiley & Sons, Ltd.

Key words: delirium experience; distress; psychological/psychiatric sequelae; relatives; staff; information provision
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Introduction

Delirium is a common syndrome with reported occurrence rates of 80% in medical intensive care units (ICU), 28% in patients following hip fracture and 22% in general medical inpatients (National Institute for Health and Clinical Excellence [NICE], 2010) Rates are also high in post-operative patients generally, cancer patients, care home residents and those in the terminal stages of life (Breitbart and Strout, 2000, Gagnon *et al.*, 2002, Siddiqi *et al.*, 2011). Risk factors for delirium are well described (Inouye, 1994, Inouye *et al.*, 1999, Litaker *et al.*, 2001). Strategies for successful delirium prevention are also reported (Inouye *et al.*, 1999, Marcantonio *et al.*, 2001, Vidan *et al.*, 2009) but are challenging to implement. This is important as delirium has an independent impact on mortality, morbidity and institutionalisation (Marcantonio *et al.*, 1994, Marcantonio *et al.*, 2000, Litaker *et al.*, 2001, Edelstein *et al.*, 2004) with a consequent bearing on length of hospital stay and significant economic implications (Rizzo *et al.*, 2001).

Less is understood about patients' experiences and recollections of delirium and any associated longer-term psychological morbidity. Furthermore, the psychological consequences of delirium can extend beyond the patient to impact relatives, carers and staff (Breitbart *et al.*, 2002, O'Malley *et al.*, 2008, Belanger and

Ducharme, 2011). The importance of the delirium experience has been recently highlighted in the NICE guideline on delirium, which advocates improved information provision to patients and relatives (NICE, 2010). The guideline encourages research into the impact of information provision on potentially reducing the severity and duration of delirium.

The literature examining the delirium experience is generally qualitative involving small numbers of patients across various populations (burns, orthopaedic/cardiac surgery, geriatric/palliative medicine and ICU). This qualitative evidence base has led to four quantitative studies describing the delirium experience (Jones *et al*., 2001, Breitbart *et al*., 2002, Bruera *et al*., 2009, Grover and Shah, 2011). Although systematic reviews on specific aspects of the delirium experience exist (Davydow *et al*., 2008, O'Malley *et al*., 2008), there is a lack of a narrative synthesis to date comprehensively drawing on both qualitative and quantitative literature and examining different populations (patients, relatives and staff) in different clinical settings (ICU, surgery and hospice care).

This review aims to fill this gap by providing clinicians with a summary of how often patients recall delirium, what is recalled, how this impacts on distress levels in patients, relatives and staff and the longer-term psychological sequelae of delirium. The impact of information provision on reducing the negative consequences of delirium will also be discussed.

A literature search was conducted in Ovid, MEDLINE, Embase, PsychINFO, British Nursing Index and Archive and PubMed between 1980 and 2011 using the terms 'delirium' combined with 'distress', 'recall', 'anxiety', 'depression', 'PTSD', 'experience' and 'patient education'. Articles were restricted to English language only.

Do patients recall their delirious episode and what factors affect this recall?

Studies in the intensive care unit population

Delirium is common in the ICU (NICE, 2010). The 'ICU syndrome' and 'ICU psychosis' are terms used interchangeably to describe psychiatric symptoms observed in ICU patients. It is now thought that these syndromes are descriptions of delirium (McGuire *et al*., 2000). Perhaps because of this ambiguity in terminology, studies involving ICU patients have suffered from a lack of consistent or robust diagnosis of delirium. Several studies report the proportions of patients who recollect factual events following ICU admission compared with those who recall confused, dreaming or delusional memories. The high incidence of delirium within the ICU coupled with the similarity in reported experiences between ICU and delirious patients makes it likely that the recall of confused, dream-like or delusional memories reported in these studies does indeed relate to delirium.

The incidence of delusional or dream-like recollections in ICU survivors varies between about 20% and 75% (Kiekkas *et al*., 2010). This wide variation may be explained by numerous factors including age, sepsis, sedation and deliberate under-reporting due to stigma from mental illness (Kiekkas *et al*., 2010). Similarly, different rates of factual recall following ICU stay are reported (Jones *et al*., 2001, Roberts *et al*., 2007, Samuelson *et al*., 2007). Unsurprisingly, factual recall is less common in those diagnosed with delirium during ICU admission (Roberts *et al*., 2007). Reports of factual and delusional recall are relevant as delusional recall has been associated with symptoms of post-traumatic stress disorder (PTSD) (Jones *et al*., 2001, Jones *et al*., 2007, Granja *et al*., 2008, Weinert and Sprenkle, 2008) and subsequent anxiety or depression (Jones *et al*., 2001, Ringdal *et al*., 2009, Kiekkas *et al*., 2010).

Non-intensive care unit studies

Variable rates of delirium recall are also reported from non-ICU populations. Much of the literature is qualitative, and samples are small. Studies range from describing 'the majority' of patients having no recall of delirium (Duppils and Wikblad, 2007) to nearly 'all' patients interviewed reporting some recall of delirium (Andersson *et al*., 2002, Cohen *et al*., 2009). In the middle of this range, Schofield reported 'just over half' the patients recalling delirium in a small study of 19 patients (Schofield, 1997). Quantitative studies also report varying proportions of patients able to recall delirium. One study in 53 hospitalised patients of all ages reports only 28% of patients recalling some aspects of delirium (Grover and Shah, 2011). Other work in patients hospitalised with cancer describes delirium recall rates from 54% to 74%, respectively (Breitbart *et al*., 2002, Bruera *et al*., 2009).

It is not immediately clear why such variations in reported rates of delirium recall exist. In attempting to explain such variation, factors associated with recall of delirium have been assessed. A qualitative study examining patients 65 years and older who underwent hip surgery, perhaps unsurprisingly, showed that patients with a lower preoperative mini mental state examination score were less likely to recall the delirious episode (Duppils and Wikblad, 2007). Similarly, short-term memory impairment, delirium severity and perceptual

disturbances were all significantly associated with a lack of delirium recall in 101 patients who suffered from delirium whilst hospitalised with cancer (Breitbart *et al.*, 2002). Recall of delirium was not significantly different according to delirium subtype (hypoactive, hyperactive and mixed-type) (Breitbart *et al.*, 2002, Bruera *et al.*, 2009). Although this may seem surprising, both studies that reported this lack of association between delirium subtype and rate of recall used the Memorial Delirium Assessment Scale (Breitbart *et al.*, 1997) to systematically identify features of delirium subtype, adding credence to a lack of association between delirium subtype and recall rates. In one study, there was a univariate association between delirium subtype and recall, but this did not persist in logistic regression, suggesting that the relationship was confounded (Breitbart *et al.*, 2002).

What do patients recall of their delirious episodes?

Predictably, the patient's experience of delirium is predominantly described by qualitative research. Typically, research involves semi-structured interviews analysed using various methods including the phenomenological hermeneutic approach, qualitative content analysis and thematic analysis. Some studies assessed patients known to have been delirious during hospitalisation (Andersson *et al.*, 2002, Duppils and Wikblad, 2007, Harding *et al.*, 2008), whereas others interviewed patients after an ICU stay without reporting whether ICU delirium had actually been diagnosed (Laitinen, 1996, Granberg *et al.*, 1998, Magarey and McCutcheon, 2005). Although the lack of a robust delirium diagnosis seems problematic, many of the themes identified are similar, suggesting that although undiagnosed during the episode, the interviewed patients were likely to have suffered from delirium.

Themes in the recollection of delirium

Although contradictory experiences are reported, several common themes emerge. These include reality and unreality (Andersson *et al.*, 2002, Magarey and McCutcheon, 2005), day–night disorientation (Laitinen, 1996, Granberg *et al.*, 1998), clouding of thought processes or seeing through a fog or mist (Andersson *et al.*, 2002), strong emotions (anger, fear, insecurity and hopelessness) (Schofield, 1997, Duppils and Wikblad, 2007, Stenwall *et al.*, 2008a), lack of control (Andersson *et al.*, 2002, Fagerberg and Jonhagen, 2002, McCurren and Cronin, 2003), past and present clouding (Schofield, 1997, Fagerberg and Jonhagen, 2002, McCurren and Cronin, 2003, Duppils and Wikblad, 2007) and misperceptions, hallucinations and delusions (Laitinen, 1996, Schofield, 1997, Granberg *et al.*, 1998, Andersson *et al.*, 2002, Fagerberg and Jonhagen, 2002, McCurren and Cronin, 2003, Duppils and Wikblad, 2007, Stenwall *et al.*, 2008a). These misperceptions, hallucinations and delusions commonly involve staff and other patients (Schofield, 1997, Crammer, 2002, Fagerberg and Jonhagen, 2002, McCurren and Cronin, 2003, Stenwall *et al.*, 2008a) and can also involve deceased family members (Magarey and McCutcheon, 2005). Communication difficulties are commonly reported with patients feeling they are not being listened to or understood (Granberg *et al.*, 1998, Andersson *et al.*, 2002, Duppils and Wikblad, 2007).

These themes are summarised in a subjective account written by a retired psychiatrist detailing his own experiences of delirium. In this account, he describes delusional recollections of surgery in other countries, attempts to 'dispose of him' when treatment had failed, deception by nursing staff and religious references to a Catholic priest. He recalls a lack of emotion and passivity, the experience of hearing but not understanding speech, misidentification of others and impaired concentration. This account neatly summarises the themes reported in the qualitative literature (Crammer, 2002).

Recollections involving family or staff

In general, the presence of family members appears beneficial to the acutely confused patient (Granberg *et al.*, 1998, Roberts *et al.*, 2007, Stenwall *et al.*, 2008a). Similarly when discussing the ICU syndrome, research suggests that the presence of a close family member can orientate the confused patient and help protect against emotions of fear, anxiety, loneliness or isolation (Eisendrath, 1980, MacKellaig, 1987, Morse, 1997, Granberg *et al.*, 1998).

Conversely, patients recall varied interactions with staff. The experience is either positive where staff are described as orientating, reassuring and kind or negative commonly involving perceptual disturbances or delusions (Laitinen, 1996, Granberg *et al.*, 1998, Crammer, 2002, McCurren and Cronin, 2003, Magarey and McCutcheon, 2005, Duppils and Wikblad, 2007). Examples of positive and negative experiences are quoted in the qualitative literature. These include patients reporting delusional recollections '. . .the nursing staff were going to kill me and sell my body parts overseas. . .' (Magarey and McCutcheon, 2005, p. 351), relief when the delirium resolved 'when I woke up next morning I

was so happy when I saw the nursing staff behave as usual and not as Nazi camp guards' (Duppils and Wikblad, 2007, p. 815) and reassurance from nursing staff 'when she (the nurse) was with me I felt I could rest for a while' (Granberg *et al*., 1998, p. 302). The role of staff in influencing a patient's experience of delirium is reflected by one study where the nursing shift change was reported as a time of 'insecurity' (Granberg *et al*., 1998).

What is the psychological and psychiatric morbidity attributed to the experience of delirium?

Distress

A study of hospitalised cancer patients conducted following resolution of delirium used a numeric scale (from 0 to 4 where 0 represents 'no distress') to record the degree of distress pertaining to the recall of delirium (Breitbart *et al*., 2002). Of the 54% of patients who recalled delirium, 80% reported 'severe' distress relating to the recollection of the episode. The mean numeric distress rating was 3.2/4 in those patients who recalled delirium with delusional symptoms as the major correlate of distress (Breitbart *et al*., 2002). These findings are replicated in another similar sized sample of cancer patients following delirium (Bruera *et al*., 2009). This study used the same questionnaire and rating scale as Breibart. The questionnaire asks patients who do not recall delirium how distressed they are that they lack memory of the episode. Overall, the median distress rating for patients in this study, regardless of whether they recalled delirium, was 2/4 (Bruera *et al*., 2009). Median distress ratings in patients who did recall delirium were higher at 3/4 as were those in family members who observed patients whilst delirious, again with a median distress score of 3/4 (Bruera *et al*., 2009).

Although intuitively we may assume that patients with hyperactive or mixed-type delirium may be more distressed than those with hypoactive delirium, in fact, the evidence suggests that the severity of distress is not affected by delirium subtype (Breitbart *et al*., 2002, Bruera *et al*., 2009). The only significant predictors of severity of distress within the delirious cancer patients studied were the presence of delusions (Breitbart *et al*., 2002) and psychomotor agitation (Bruera *et al*., 2009).

The relationship between short-term distress and longer-term psychological or psychiatric morbidity is not yet fully understood.

Post-traumatic stress disorder

In a recent systematic literature review, the median point prevalence of PTSD in ICU survivors was between 19% and 22% depending on differing diagnostic methods (either questionnaire-ascertained 'clinically significant' symptoms of PTSD or 'clinician-ascertained' PTSD) (Davydow *et al*., 2008). This review included studies with follow-up periods from less than 1 month up to 2 years after ICU admission. The link between ICU delirium and the development of PTSD has been examined (Girard *et al*., 2007, Roberts *et al*., 2007). No significant association between delirium and PTSD has been shown; however, this may be due to inadequate diagnoses of delirium or a lack of statistical power (Davydow *et al*., 2008). A lack of significant association between delirium and PTSD could be questioned because 'frightening or psychotic experiences' in ICU, both of which are commonly features of delirium, are consistently cited as predictors for the subsequent development of PTSD (Jones *et al*., 2001, Jones *et al*., 2003, Jones *et al*., 2007, Davydow *et al*., 2008). A short case series in transplant patients also reports delirium-associated delusions and hallucinations as a provocation for PTSD (DiMartini *et al*., 2007). This potential association needs clarification in larger scale adequately powered studies using robust diagnoses both of PTSD and of incident delirium.

Anxiety and depression

Patients who suffered from delirium within 4 weeks of myeloablative hematopoietic cell transplantation displayed worse symptoms of depression and anxiety as well as greater fatigue than transplant patients without delirium (Fann *et al*., 2007, Basinski *et al*., 2010). These effects were seen initially after transplantation but persisted at 12-month follow-up. The impact of delirium on anxiety and depression also persisted following adjustment for numerous potential confounders including demographic factors, years of education, disease severity, comorbidity, prior chemoradiotherapy, complications of transplantation, use of glucocorticoids and pain score. Although scores of mental health functioning and cognitive assessment were undertaken at baseline, these are not listed in the table of confounders adjusted for in the analysis (Fann *et al*., 2002, Fann *et al*., 2007, Basinski *et al*., 2010).

A literature review examining depression and anxiety after delirium reported a mean prevalence of clinically significant depressive symptoms, up to 2 years after a

delirious event, of 31% (range 4–47%) (Davydow, 2009). Lifetime prevalence of psychopathy within this study was quoted at between 35% and 67% (with depression +/− dementia included together). No data on comparative rates of depressive symptoms in an age-matched population were cited in the paper. However, for comparison purposes, the National Health and Nutrition Examination Survey data (2005–2008) reported a prevalence of 20.1% of adults with depressive symptoms according to the Patient Health Questionnaire-9 (PHQ-9) (Shim *et al.*, 2011). It was not possible from this work to attribute depressive symptoms directly to the delirium, and the author acknowledges that this psychological morbidity may be due to other factors, for example, the treatment of delirium (Davydow, 2009). As with the correlation between PTSD and recall of delirium, the association between anxiety, depression and delirium needs further exploration.

What effect does delirium have on patient's relatives?

The impact of observing delirium on the relatives or carers of patients is significant. A qualitative study used content analysis to describe distress in the relatives of terminal care patients who had suffered from delirium and found that 70% of families expressed distress at observing delirium in their relatives (Namba *et al.*, 2007). This distress was reported in relation to 'guilt', 'anxiety and worry', 'helplessness' and 'exhaustion' (Namba *et al.*, 2007). Similar findings are reported by another study examining the relatives of patients with advanced cancer who described their experiences as 'stressful', 'terrible', 'frustrating' and 'scary' (Cohen *et al.*, 2009). Notably though, those who had expected 'confusion' found the experience less distressing. Although it can be difficult to disentangle the distress related to the observation of delirium and the distress related to terminal illness, the findings of these studies are substantiated by other qualitative work using a descriptive phenomenological approach in non-terminal patients (Stenwall *et al.*, 2008b). Relatives in this work reported feelings of 'loss', 'mistrust' and 'insecurity' when dealing with the unfamiliar behaviour of a familiar person with an acute confusional state (Stenwall *et al.*, 2008b).

Not only is distress reported by a significant proportion of those families who observe delirium but also the degree of distress they report is considerable (Breitbart *et al.*, 2002, Bruera *et al.*, 2009). Seventy-six per cent of spouses or caregivers of cancer patients with delirium rated their distress at witnessing delirium as 'severe' (Breitbart *et al.*, 2002). These spouse/caregiver ratings of distress were higher than those reported by the patients who had suffered the delirium (mean numeric distress ratings of 3.75/4 in relatives and 3.2/4 in patients) (Breitbart *et al.*, 2002).

A study of 200 unpaid caregivers of patients with advanced cancer assessed generalised anxiety in caregivers in association with caregiver-observed delirium/confusion in the patient (Buss *et al.*, 2007). The reported incidence of generalised anxiety amongst carers was 3.5%. Caregivers who perceived the patient to have recently suffered from delirium were 12 times more likely to meet criteria for generalised anxiety than those who had not observed delirium or confusion (Buss *et al.*, 2007). This relationship persisted after adjusting for caregiver burden, suggesting that carer anxiety is not solely related to the increased demands of care in patients with delirium.

Family members of patients recovering from an ICU stay are at risk of developing PTSD (Jones *et al.*, 2004, Azoulay *et al.*, 2005, Griffiths and Jones, 2007) with incidence rates quoted at 49% in one study (Jones *et al.*, 2004). It is probable that PTSD in relatives relates to the trauma of a relative's critical illness and not solely to the observation of delirium. However, the distress caused to relatives by observing delirium coupled with the frequency of delirium in ICU patients suggests that delirium may be a potential contributor to the subsequent development of PTSD.

What effect does delirium have on staff?

It is acknowledged that caring for a patient with delirium can also impact negatively on staff. Most of the work examining this explores the impact of delirium on nursing staff as they tend to be most frequently and closely in contact with patients. Two literature reviews examining the effect of delirium on nursing staff summarise the themes identified in the qualitative literature (O'Malley *et al.*, 2008, Belanger and Ducharme, 2011). These include 'stress due to the unpredictability of delirium and workload', 'uncertain situations', 'issues of safety', 'patients keeping a distance or being suspicious of nurses', 'difficulties reaching patients', 'deciding when to be flexible and when to be in control', 'barriers such as the care environment not meeting needs of older adults' and 'understanding their experiences' (O'Malley *et al.*, 2008, Belanger and Ducharme, 2011). Breitbart *et al.* (2002) surveyed 101 nursing staff involved in the care of cancer patients with delirium and reported that 73% suffered severe distress with a mean distress score of 3.09/4 on a numeric

scale. The strongest predictors of nursing distress were delirium severity and perceptual disturbances (Breitbart *et al*., 2002). In contrast, another study surveyed the impact of delirium on bedside cancer nurses, advanced nurse practitioners and palliative care physicians and reported a very low mean distress rating of 0/4 (Bruera *et al*., 2009). The discrepancy between the results of these two studies, examining similar staff populations, is not easily explained. The authors of the most recent paper suggest several potential explanations for this observed difference (Bruera *et al*., 2009). These include possible bias from surveying only daytime nursing staff (delirium may be worse at night-time or staff may feel more isolated at night-time), better symptom control in their patient population reducing the distressing impact on attending staff or the impact of training and support for bedside staff in minimising distress (Bruera *et al*., 2009). Overall, however, when taken in context of the themes identified in the qualitative literature, it appears that managing patients with delirium is a stressful event for nursing staff. It is not yet fully understood whether and how education and training could minimise the distress attributed to professionally caring for a patient with delirium.

What is the role of information provision in reducing delirium and the associated negative sequelae?

Provision of information after the event

Intensive care unit diaries summarise events during an individual patient's ICU stay in lay terminology and are designed for the patient to read once they have recovered. These diaries have been shown in a randomised controlled trial to reduce psychological morbidity and decrease the incidence of new PTSD following ICU stay (Jones *et al*., 2010). On the basis of expert opinion (DH and Modernisation Agency, 2003), many UK hospitals now run ICU follow-up clinics to identify ongoing physical and psychological issues affecting patients after intensive care treatment. The evidence base for ICU follow-up clinics is under review at present (Cuthbertson *et al*., 2007). Similarly, the concept of 'debriefing' patients after a delirious episode is suggested by O'Malley *et al*. (2008). Such a 'debrief' following an episode of delirium may involve explanation of delirium, reassurance regarding recovery, information on reducing the risk of future recurrence of delirium and written information designed for patients and their relatives. At present, there is insufficient evidence to support debriefing after delirium, but this remains a possibility for future research.

Provision of information prior to the event

Other work has examined the impact of pre-emptive information provision on reducing adverse delirium-related outcomes. A quasi-experimental study published 30 years ago tested the hypothesis that preoperative education about the possibility of unusual sensory or cognitive experiences (common in post-operative delirium) would reduce the occurrence of these experiences or allow for better coping strategies (Owens and Hutelmyer, 1982). Sixty-four patients undergoing cardiac surgery were consecutively assigned to intervention or control groups. A researcher discussed the possibility of developing post-operative perceptual disturbances, impaired concentration and cognitive difficulties with the intervention group. In post-operative interviews, there was no significant difference in the occurrence of 'unusual experiences' between the control and experimental groups. However, the intervention groups reported feeling significantly more 'comfortable' than the control groups during these unusual experiences (Owens and Hutelmyer, 1982). Notably, this study did not use a DSM-IV diagnosis of delirium and simply reported unusual perceptual disturbances. Although randomisation and formal delirium diagnosis would make this work more robust, it should pave the way for further studies assessing the role of pre-emptive information provision in reducing delirium-related distress.

Impact of information for patients

The qualitative literature consistently reports that patients following hip surgery and ICU admission desire information about symptoms of delirium (Laitinen, 1996, Magarey and McCutcheon, 2005, Duppils and Wikblad, 2007). Patients reported the importance of knowing that unreal experiences were common (Granberg *et al*., 1998) and stated that knowledge about events and plans for their ongoing care helped them to feel safe and reassured (McCurren and Cronin, 2003, Stenwall *et al*., 2008a). In addition, patients who experience delirium with perceptual disturbances are reluctant to mention this to staff (O'Malley *et al*., 2008). This raises the need for training regarding delirium for staff working with older or at-risk patient groups. Staff should be taught to proactively question patients regarding perceptual disturbances and other symptoms of delirium. This may

facilitate the effective provision of information in a timely manner to both patients and their relatives.

Impact of information for families

Similar findings are seen in studies focussing on the role of communication in the families of patients with delirium (Morita *et al.*, 2007, Namba *et al.*, 2007, Cohen *et al.*, 2009). A qualitative study interviewed bereaved family members of cancer patients who had developed delirium at the end of life and led to the proposal of several strategies to reduce the distress associated with witnessing delirium (Namba *et al.*, 2007). These strategies provide a framework for effective communication for health care staff caring for delirious patients. They include 'respecting the patient's subjective world', 'treating the patients the same as before' and providing 'information support' (Namba *et al.*, 2007). The effects of information provision were studied in the family caregivers of patients suffering from delirium in a hospice (Gagnon *et al.*, 2002). A psychoeducational intervention involving nurse-led discussion and a brochure explaining delirium was evaluated using a before and after study. Prior to receiving the intervention, family members did not know what delirium was or that it could be treated (Gagnon *et al.*, 2002). The families receiving the intervention felt more equipped to make decisions than those receiving 'usual care', and overall, participants felt that family caregivers should be proactively educated about delirium (Gagnon *et al.*, 2002). Notably though, 2 weeks after the death of the patient, 24.3% of relatives did not recall having received the nursing intervention (these relatives were significantly older). The importance of 'treating the patient as before' was also highlighted by Stenwall *et al.* (2008b) who concluded that the relative's knowledge of the patient should inform the style of communication used and should be tailored to the individual patient encounter.

Limitations of this review

No large-scale studies exist describing the delirium experience or how to effectively ameliorate the impact of the condition. In terms of generalisability to adult patients as a whole, the literature in this field is over-represented by studies examining intensive and palliative care patients, and the heterogeneous nature of the populations studied may limit interpretation of the findings. However, despite these accepted limitations, the reported results are similar, suggesting that regardless of underlying cause, the recall and experience of delirium for patients and the impact on relatives and professional carers display consistent themes.

By inclusively describing results from methodologically different studies in a diverse patient population, this review aims to provide a clinically meaningful summary of the delirium experience from the perspectives of patients, relatives and staff. The acknowledged shortcomings in both the published work and therefore this review should be addressed by future research in this field.

Future research

NICE delirium guidance (2010) highlights a lack of knowledge about the 'delirium experience' and advocates research into effective provision of information to patients and carers regarding delirium. This research should address whether the provision of information decreases the occurrence, duration or severity of delirium and whether there is an impact on patient and family delirium-related distress. NICE questions whether training informal family carers about delirium could improve early recognition of this condition and thus impact severity or duration. The answers to these questions may inform the process of assessment and counselling of patients at risk of delirium and their families. This has implications for numerous care settings including care homes, hospices, preoperative clinics and prechemoradiotherapy clinics where patients at high risk of developing delirium are commonly encountered. Similarly, the role of educational programmes aimed at improving knowledge and coping strategies in professional carers and nurses may serve to alleviate the distress caused to staff (Milisen *et al.*, 2004). This may have a secondary effect in improving explanation and reassurance to patients and their families during an episode of delirium.

Conclusion

In summary, we know from the evidence that patients may recall delirium and that this recall or the observation of delirium causes distress to patients, relatives and staff. Several common themes in the experience of delirium are identified in the literature including day–night disorientation, issues with communication difficulty and delusional thoughts. Furthermore, evidence of the longer-term psychological sequelae of delirium is emerging with the suggestion that delirium

may increase the subsequent incidence of symptoms of anxiety and depression.

The link between distress and psychological morbidity is incompletely understood and should be explored in future research. Although there are suggestions that information provision may help to reduce the distress attributed to delirium for both patients and relatives, this requires robust examination. Depending on the nature of the patient's illness and the urgency of presentation, proactive education for those at risk may be feasible, for example, in elective surgical patients. For other patients, pre-emptive education about delirium will not be possible because of emergency presentation, and in this group, the possibility of follow-up care for patients after delirium should be evaluated.

Pending better evidence but on the basis of the current literature, we advocate pre-emptive and post-event delirium education aimed at patients and relatives and including written material. Staff working with those at risk of delirium should receive training about the condition with the aim of both reducing the distress for patients and relatives and minimising the negative impact of observing delirium on staff.

Key points

- Regardless of subtype (hypoactive, hyperactive and mixed-type), delirium is often distressing for patients who recollect it.
- The experience of delirium may put patients at increased risk of psychiatric and psychological symptoms in the future.
- Distress at observing delirium in a relative can be greater than the distress reported by the patient themselves.
- Caring for patients with delirium can be stressful for professional carers.
- The role of information provision in reducing distress related to delirium should be researched in patients and their relatives.

Conflict of interest

None declared.

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As with other patient reported outcomes the issue of delirium distress is therefore relatively underreported in the academic literature. Based on this literature review (6.1) and the views of patients and their relatives noted in the process of co-production and co-design, this study aimed to;

- describe the distress related to an episode of postoperative delirium in older surgical patients and their relatives using the distress thermometer
- examine the association between degree of distress and features of delirium on the Delirium Rating Scale both on resolution of delirium and at 12 month follow up
- examine the association between recall of delirium and features of delirium on the Delirium Rating Scale

6.2 Methods – observational study

Ethics

Ethical approval for this study was granted (13/LO/0293)

According to sections 30-34 of the Mental Capacity Act (2005) ethical approval was sought and granted to recruit patient participants who lacked capacity to consent. In these cases, a consultee was approached and asked to provide written assent on behalf of the participant. This approach was taken as due to the necessary inclusion of those with delirium a lack of capacity to study participation was anticipated to be high and without this specific ethical approval recruitment would have been problematic and results potentially biased.

The methods are described in the paper presented in 6.3. The study questionnaires can be seen in appendices 17, 18. The patient/relative and consultee information sheets and consent forms can be seen in appendices 19-22.

Limitations

The predominant limitation to this study was the lack of a control group. If it had been feasible to do so, comparing distress scores between postoperative patients with delirium and matched postoperative controls without delirium would have been useful in determining how much of the stated distress related to delirium as opposed to the experience of being unwell and undergoing surgery. A further limitation relates to the operational challenge of measuring the emotional concept of distress. Attempts to mitigate this were made through using a validated and endorsed tool, the distress thermometer. However, this does not fully negate the difficulty of describing an emotional response through a numeric scale. Finally, the significant number of study participants who were lost to follow up at 12 months limited the ability to draw longer term conclusions. It was unclear why such an attrition rate occurred although site file notes refer to death and change of address in several cases.

6.3 Results

Contribution of each co-author to publication

Judith Partridge, Danielle Harari, Jugdeep Dhesi and Finbarr Martin conceived and designed this study including development and refinement of the questionnaires used. Judith Partridge and Elizabeth Biswell acquired the data with analysis undertaken by Judith Partridge supported and advised by Siobhan Crichton, Jugdeep Dhesi and

Danielle Harari. Judith Partridge drafted the manuscript and Jugdeep Dhesi and Finbarr Martin critically appraised and revised the paper.

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RESEARCH ARTICLE

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Measuring the distress related to delirium in older surgical patients and their relatives

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Objectives: Delirium is a common postoperative complication with implications on morbidity and mortality. Less is known about the psychological impact of delirium in patients and relatives. This study aimed to

a. quantitatively describe distress related to postoperative delirium in older surgical patients and their relatives using the distress thermometer,
b. examine the association between degree of distress and features of delirium on the Delirium Rating Scale (DRS), and
c. examine the association between recall of delirium and features of delirium on the DRS.

Methods: This prospective study recruited postoperative patients and their relatives following delirium. The distress thermometer was used to examine the degree of distress pertaining to delirium and was conducted during the hospitalization on resolution of delirium and then at 12-month follow-up. Associations between delirium-related distress in patient and relative participants and severity and features of delirium (DRS) were examined.

Results: One hundred two patients and 49 relatives were recruited. Median scores on the distress thermometer in patients who recalled delirium were 8/10. Relatives also showed distress (median distress thermometer score of 8/10). Associations were observed between severity and phenotypic features of delirium (delusions, labile affect, and agitation). Distress persisted at 12 months in patients and relatives.

Conclusion: Distress related to postoperative delirium can be measured using a distress thermometer. Alongside approaches to reduce delirium incidence, interventions to minimize distress from postoperative delirium should be sought. Such interventions should be developed through robust research and if effective administered to patients, relatives, or carers.

KEYWORDS

carer and relative distress, distress thermometer, older people, postoperative delirium, psychological and emotional distress

1 | INTRODUCTION

Delirium is a common postoperative complication occurring in 20% of hospital inpatients.[1] It has significant implications in terms of increased morbidity and mortality rates.[2,3] Less is understood about patients' experiences of delirium and the longer-term psychological morbidity attributable to the condition. Furthermore, the psychological consequences of delirium may extend to involve relatives who observe the episode. With the increasing awareness of the importance of patient-related outcome measures, describing the delirium experience for both patients and relatives is advocated in the National Institute for Health and Care Excellence (NICE) guideline on delirium.[4]

To date, the research examining the delirium experience has been conducted in heterogeneous patient populations including critical care survivors, orthogeriatric patients, and those receiving end-of-life care, and the quantitative studies have predominantly recruited patients with cancer. Overall, these studies suggest that in more than half of cases, patients do recall delirium and that this recollection can be distressing. Distress can be even greater in relatives witnessing delirium and may result in longer-term psychological sequelae.[5-13]

Distress related to a diagnosis of cancer has been increasingly described in the oncology literature. It is thought to affect participation in treatment, quality of life, and satisfaction with treatment.[14,15] Various brief tools to detect distress in busy clinical environments have been developed and evaluated.[16,17] The distress thermometer (DT) is a self-completion tool that asks patients to rate how distressed they have felt in the last week on a scale ranging from 0 (*not distressed*) to 10 (*extremely distressed*). It has been incorporated by the National Comprehensive Cancer Network (NCCN)[18] with a suggested optimal cutoff[19] for detecting significant distress of 3. When compared against the Hospital Anxiety and Depression Scale (HADS) for detecting anxiety and depression in a sample of patients with cancer and using a cut point of 3, the DT showed sensitivity of 0.84 and specificity[16] of 0.80 with area under the curve (AUC) 0.69.

While prevention of delirium remains paramount, interventions to minimize the distress associated with delirium should be developed in parallel. In order to assess potential interventions to reduce delirium-related distress, a fuller understanding of the characteristics and impact in the postoperative population is required.

1.1 | Objectives

The objectives of this study are the following:

a. to quantitatively describe the distress related to an episode of postoperative delirium in older surgical patients and their relatives using the DT,
b. to examine the association between degree of distress and features of delirium on the Delirium Rating Scale (DRS)[20] both on resolution of delirium and at 12-month follow-up, and
c. to examine the association between recall of delirium and features of delirium on the DRS.

Key points

- Postoperative delirium is distressing for patients who recall the experience and relatives who observe it.
- Severity and duration of delirium are associated with degree of distress.
- Presence of delusions, abnormal thought processes, labile affect, language disturbance, agitation, and disorientation are associated with degree of distress.

2 | METHODS

This observational study was set in an inner city teaching hospital in London. Consecutive patients undergoing surgical procedures (gastrointestinal, orthopedic, urological, or vascular) between June 2013 and May 2014 who met the inclusion and exclusion criteria below were eligible for recruitment.

2.1 | Criteria

2.1.1 | Inclusion criteria

A

1. Aged 65+
2. Surgical inpatients following operative procedure (orthopedic, upper and lower gastrointestinal, vascular, and urology)
3. Postoperative delirium, diagnosed using the Confusion Assessment Method (CAM)[21]

B

Attending relatives of those patients recruited (if they observed the delirium)

2.1.2 | Exclusion criteria

1. Severe cognitive impairment limiting the ability to read, comprehend, or complete short questionnaire
2. Patient judged by their attending doctors to be dying and close to death
3. Patients or relatives unable to speak sufficient English to participate in the study without the use of a translator

2.2 | Recruitment and consent

Patients[22] who screened positively (≥4) on the 4AT were assessed for delirium using the CAM. Those without delirium continued to receive daily screening using CAM in case delirium developed during the

admission. 4AT negative patients were also flagged to the research team if the usual care team noted clinical features of delirium (eg, drowsiness, inattention, and fluctuation throughout the day). Once delirium was diagnosed, the capacity of the patient to consent to participation in the study was assessed by a research fellow or nurse in accordance with the Mental Capacity Act (2005). Patients with capacity signed a written consent form after verbal and written explanation of the study. Those who lacked capacity were managed according to sections 30 to 34 of the Mental Capacity Act (2005) with the use of a personal or nominated consultee.

Relatives (one or more) of patient participants were also approached for recruitment and consented, if they had observed the episode of delirium. They were identified through patient participants. Initial contact was made either by the research team on the ward or by telephone.

2.3 | Tools

The DRS R98 was used to examine features of the delirium. This validated tool is a 16-item scale with a maximum total scale score of 46 points (includes three diagnostic items) and a maximum severity score of 39 points. It has good internal reliability (Cronbach's α coefficient of 0.9) and good interrater reliability.[22]

The degree of delirium-related distress was measured using the DT described previously. Originally designed to measure cancer-related distress, this tool was piloted in preliminary work showing acceptability to patients and nursing staff. No adaptions were made to the tool for this study.

2.4 | Data collection

Once recruited and consented, patients were assessed daily using the DRS in order to ascertain the severity, duration, and specific symptoms of delirium, eg, presence of delusional symptoms or motor agitation, etc. Drugs used to treat delirium were recorded (antidopaminergics or benzodiazepines). The surgical procedure, nature of admission (ie, elective or emergency), and baseline demographic and medical data were recorded. In patients who had undergone elective surgery, it was noted whether any verbal or written information on the risk of postoperative delirium had been recorded as having been provided.

Following resolution of delirium, participating patients and relatives completed a short questionnaire about their recall and experience of delirium (Data S1). Patients also underwent brief cognitive assessment using the Montreal Cognitive Assessment (MoCA)[23] and completed an HADS[24] questionnaire. This initial questionnaire and cognitive assessment was undertaken up to a week after delirium resolution while the patient was still an inpatient. The questionnaire was repeated at 12 months after resolution of delirium.

2.5 | Sample size calculation

Using pilot data (examining delirium-related distress measured on the DT in older postoperative patients), the sample size was calculated at 68 patients (based on a standard deviation of 2.1 and a standard error of 1). Assuming (based on previous literature[5]) that between one half and two thirds of patients will recall the delirium, we aimed to recruit 102 patients.

2.6 | Data analysis

Patient characteristics were summarized as frequency (percentage), mean (standard deviation), or median (interquartile range). Age of patients who recalled delirium was compared with those who did not using the *t* test, the number of comorbidities and disease severity was compared using the Mann-Whitney test, and all other characteristics were compared between the two groups using chi-squared or Fisher's exact tests, as appropriate. Correlations between distress score and continuous characteristics (age, number of comorbidities, and disease severity) were assessed using Kendall's Tau-b, and distress scores were compared across other characteristics using the Mann-Whitney test for two groups and the Kruskal-Wallis test for three or more. Associations between relative distress scores, patient characteristics, and disease severity were explored in the same way. Analysis was conducted using data from all participating relatives, followed by a sensitivity analysis where one relative was randomly selected (where two or more relatives provided data relating to the same patient).

Characteristics associated with the odds of remembering delirium were identified using multivariable logistic regression, and then, linear regression used models to identify characteristics associated with degree of distress among only those who recalled delirium. For both models, factors, which had a *p* value of less than .1, in invariable analysis were carried forward to multivariable models, which also adjusted for age. Insignificant variables were then removed using backwards elimination.

In analysis of delirium severity, the mean DRS was used. A sensitivity analysis was carried out in which highest DRS scores were used instead. Parameter estimates and *p* values were very similar, and choice of scoring algorithm did not alter conclusions, and so, only results using means are presented.

Analysis was conducted using the STATA 13MP.

3 | RESULTS

One hundred and thirteen potential patient participants were approached of whom 62 had capacity to consent. One hundred and two patient participants were recruited into the study (Figure 1). Nine potential patient participants with capacity declined with the majority of these stating that they did not want to discuss the delirium. Two personal consultees declined on behalf of potential patient participants without capacity. Forty-three relative participants were approached, and all consented to study participation (Figure 1).

The relationships between patient characteristics and recall of delirium are summarized in Table 1. The likelihood of recalling delirium did not differ significantly across any of the patient characteristics.

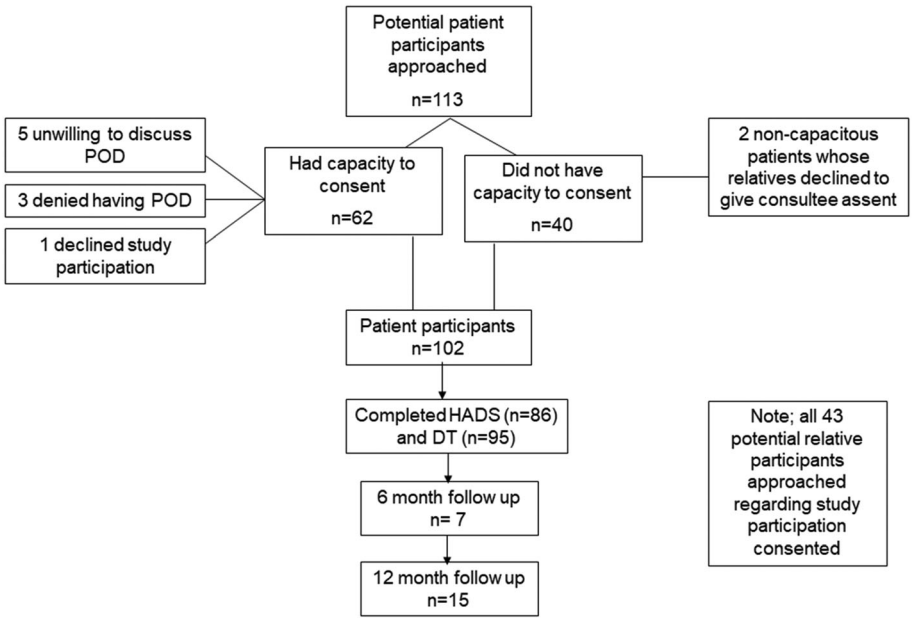

FIGURE 1 Recruitment to study

TABLE 1 Patient recall of delirium by patient characteristics

	All (n, %)	Did Not Recall Delirium (n, %)	Recalled Delirium (n, %)	*P* Value
All	102	27	67	
Age, mean (SD)	78.7 (7.3)	80.0 (7.5)	78.5 (7.3)	.383
White ethnicity	87 (88.8)	23 (85.2)	56 (85.6)	.999
12+ years in education	14 (16.9)	4 (14.8)	10 (14.9)	.950
Male	69 (67.7)	16 (59.3)	47 (70.1)	.310
Current smoker	17 (17.0)	5 (18.5)	10 (14.9)	.894
Alcohol consumption (per wk)				
None	41 (42.7)	14 (51.9)	24 (35.8)	.386
<15 units (f) or <22 units, m	35 (36.5)	7 (25.9)	25 (37.3)	
>14 units (f) of >21 units, m	20 (20.8)	5 (18.5)	13 (19.4)	
Number of comorbidities, median (IQR)	5.5 (4-8)	6 (4-8)	6 (4-8)	.987
Elective surgery	49 (48.0)	13 (48.1)	32 (47.8)	.973
Surgical subspecialty				
Urological	12 (11.8)	2 (7.4)	7 (10.4)	.296
GI	21 (50.6)	6 (22.2)	13 (19.4)	
Vascular	50 (49.0)	11 (40.7)	36 (53.7)	
Orthopedic	17 (16.7)	6 (22.2)	11 (16.4)	
Head and neck	1 (1.0)	1 (3.7)	0	
Gynecological	1 (1.0)	1 (3.7)	0	
History of cognitive impairment	77 (75.5)	19 (70.3)	52 (77.6)	.596
Recalled delirium	67 (71.3)	NA	NA	
Drugs used to treat delirium	33 (32.4)	10 (37.0)	18 (26.8)	.332
Patient warned of possibility of delirium	14 (14.9)	5 (18.5)	9 (13.4)	

Abbreviations: GI, gastrointestinal; IQR, interquartile range; NA, not applicable; SD, standard deviation.

The median distress score on the DT was 6 (interquartile range [IQR] 2-9) and differed significantly between those who did and did not recall delirium (patients who recalled: median = 8 [4-9] versus 2 [0-5] in those who did not, $p < .001$). There was also a weak negative correlation between distress score and age in all patients ($\tau = -0.16$, $p < .033$) and a slightly weaker but nonsignificant correlation in only patients who recalled delirium ($\tau = -0.14$, $p = .118$). No association was seen between level of distress and other baseline patient characteristics across the whole group or if those who recalled delirium were analyzed separately (Table S1). As per our hypothesis, the level of distress was higher in those who recalled delirium. There was no difference in delirium-related distress between those patients who received preoperative verbal or written information on the risk of postoperative delirium and those who did not.

The relationships between severity of delirium, recall of delirium, and distress are summarized in Table 2. The first columns compare distress scores in those who did and did not recall delirium while the last two summarize the correlation between mean DRS and distress. Perceptual disturbance, delusions, and lability of affect were all significantly associated with degree of distress.

Data were collected from 43 relatives of 38 patients. The median level of distress recorded on the DT in relatives who witnessed delirium was 8/10 (7-9). Carer distress increased significantly with duration of delirium ($\tau = 0.307$, $p = .009$). DRS severity score ($\tau = 0.363$, $p = .002$) and total score (0.318, $p = .006$) were also positively associated with carer distress. The individual features associated with carer distress were lability of affect ($\tau = 0.744$, $p = .021$), language ($\tau = 0.253$, $p = .034$), thought process ($\tau = 0.386$, $p = .001$), motor agitation ($\tau = 0.264$, $p = .001$), and orientation ($\tau = 0.296$, $p = .015$). In a sensitivity analysis, one relative was randomly selected for the five patients where two provided data. Findings were unchanged when analysis was repeated on this subsample (Table S2).

Finally, models were fitted to identify factors that were independently associated with patient recall of delirium and distress. Logistic regression was used to identify factors (patient characteristics and DRS items) associated with recall of delirium after adjusting for age. In these models, perceptual disturbance was the only factor identified to significantly influence recall of the delirious episode (OR = 1.94; 95% CI, 1.19-3.17, $p = .008$). Linear models were used to examine features of delirium associated with higher distress scores. Only emergency surgery was significant after adjustment for age ($\beta = -2.6$; 95% CI, −5.2-−0.1, $p = .044$).

Next, the associations between features of delirium/delirium severity and distress at 6 and 12 months in patients and carers were explored (Table 3). In patients, at 12 months, the duration of delirium

TABLE 2 Associations between patient recall of delirium/degree of distress and the DRS

	All (Median [IQR] or Mean [SD])	Did Not Recall Delirium (Median [IQR] or Mean [SD])	Recalled delirium (Median [IQR] or Mean [SD])	*P* Value	Distress[a] Kendall's τ	*P* Value
Delirium duration	4 (2-7)	5 (2-7)	3 (2-5)	.484	0.14	.142
DRS (mean) severity score	19.8 (6.6)	18.7 (5.5)	20.3 (6.9)	.280	0.202	.023
DRS (mean) severity items						
Sleep-wake cycle	2 (1-2)	2 (1-2)	2 (1-2)	.632	0.101	.290
Perpetual disturbance	1.2 (0.7-2.3)	1 (0-2)	1.6 (1-3)	.010	0.012	.903
Delusion	1 (0.5-2)	0.7 (0-1.7)	1 (0.5-2)	.029	0.198	.034
Lability of affect	2 (1.3-2.2)	2 (1-2)	2 (1.3-2.2)	.275	0.238	.012
Language	1 (0.3-1)	0.9 (0.3-1)	1 (0.3-1.4)	.374	−0.009	.928
Thought process	2 (1.7-3)	2 (1.5-2.3)	2 (1.7-3)	.076	0.152	.110
Motor agitation	1.5 (0.6-2)	1.5 (0.5-2)	1.5 (0.5-2)	.751	0.126	.174
Motor retardation	0.5 (0-1.5)	1.5 (0.5-2.8)	1 (0-2)	.270	−0.102	.287
Orientation	2 (1.5-2)	2 (1.5-2)	2 (1.5-2)	.618	−0.015	.877
Attention	2 (1.6-2.7)	2 (1.5-2.7)	2 (1.5-3)	.831	0.053	.582
Short-term memory	2 (1.5-3)	2 (1.5-3)	2 (1.5-2.7)	.840	0.142	.135
Long-term memory	0 (0-1)	0 (0-1)	0 (0-0.7)	.479	0.322	.001
Visiospatial	1.6 (1-2)	1.8 (1-2.8)	1.6 (1-2)	.464	0.131	.164
Temporal onset of symptoms score	3 (2-3)	3 (2-3)	3 (2-3)	.387	0.001	1.000
Fluctuation of symptoms score	1 (1-2)	1 (1-2)	1 (1-2)	.089	0.174	.099
Physical disorder score	2 (2-2)	2 (2-2	2 (2-2)	.033	−0.193	.079
DRS (mean) total score	26.0 (5.8)	24.2 (6.1)	26.3 (5.8)	.122	0.170	.063

Abbreviations: DRS, Delirium Rating Scale; IQR, interquartile range.

[a]Patients who recalled delirium only.

TABLE 3 Associations between DRS and degree of distress at follow-up in patients who recalled delirium and their carers

	Patient Distress[a]				Carer Distress			
	6 mo (n = 7)		12 mo (n = 15)		6 mo (n = 5)		12 mo (n = 6)	
	Kendall's τ	*P* Value	Kendall's τ	*P* Value	Kendall's τ	*P* Value	Kendall's τ	*P* Value
Baseline distress	−0.55	.125	0.177	.416	0.134	1.00	0.276	.566
Delirium duration	−0.15	.759	0.453	.041	0.252	.776	0.356	.492
DRS (mean) severity score	−0.450	.219	−0.183	.391	0.756	.154	0.714	.080
DRS (mean) severity items								
Sleep-wake cycle	−0.067	1.000	−0.126	.613	0.134	1.000	−0.214	.697
Perpetual disturbance	−0.231	.612	−0.011	1.000	0.429	.533	−0.414	.339
Delusion	−0.103	.877	0.089	.715	0.429	.533	0.297	.552
Lability of affect	0.000	1.000	0.123	.599	0.756	.154	0.643	.120
Language	−0.418	.304	−0.298	.185	0.252	.776	−0.309	.545
Thought process	−0.264	.526	−0.461	.038	0.429	.533	0.077	1.000
Motor agitation	−0.550	.125	−0.262	.233	0.252	.776	0.661	.159
Motor retardation	−0.109	.873	0.057	.831	−0.143	1.000	0.232	.682
Orientation	−0.418	.304	−0.475	.034	0.714	.213	−0.232	.682
Attention	−0.380	.336	−0.121	.623	0.571	.350	0.161	.835
Short-term memory	−0.685	.059	−0.241	.294	0.267	.769	0.178	.819
Long-term memory	−0.194	.721	−0.041	.903	0.378	.693	0.445	.360
Visiospatial	−0.513	.162	−0.057	.833	0.252	.776	0.694	.106
Temporal onset of symptoms score	0.000	1.000	0.295	.233	0.000	1.000	0.598	.235
Fluctuation of symptoms score	−0.194	.721	0.233	.351	−0.378	.693	0.756	.100
Physical disorder score	−0.183	.801	0.000	1.000	0.000	1.000	0.000	1.000
DRS (mean) total score	−0.586	.095	−0.140	.540	0.756	.154	0.857	.032

Abbreviations: DRS, Delirium Rating Scale; IQR, interquartile range.

[a]Patients who recalled delirium only.

was positively correlated with degree of distress. Orientation and thought process was negatively associated with distress. Though sample sizes are very small, it does appear that there is a high correlation at both 6 and 12 months between the mean DRS score and distress in carers.

4 | DISCUSSION

This is the first study to explore the level of distress related to postoperative delirium in patients and their relatives and describe the features of delirium most associated with delirium-related distress. It shows considerable delirium-related distress in those who recall postoperative delirium (median score on DT 8/10 [4-9]) with distress scores seen in relatives who observed delirium (median score on DT 8/10 [7-9.5]). While no associations exist between baseline patient characteristics and delirium-related distress, clear associations were observed between the severity of delirium (measured using DRS) and phenotypic features of delirium and level of delirium-related distress. Clinical features associated with distress were similar in patients and relatives and include duration of delirium, presence of delusions, abnormal thought processes, labile affect, language disturbance, agitation, and disorientation.

There were limitations to this study. In particular, data were only available from relatives of 38 of 102 patients, and follow-up data were only provided from seven and 15 patients at 6 and 12 months, respectively. Although the available data can give some indication of the long-term impact of delirium on distress of patients and carers in the long term, a larger sample would be need to explore this further in order to negate the impact from possible bias due to noncompletion of longer-term follow-up. Furthermore, the measurement of the emotional concept of distress is inherently problematic. Attempts to mitigate this were undertaken in this study by using the DT, which has already been validated in the measurement of cancer-related distress and is endorsed for use clinically by the NCCN. The potential for recruitment bias exists, and within this study, no conclusive comment can be made on whether those with a traumatic experience of delirium were more or less likely to participate. Of note though, in the co-design of the study, offering an opportunity to discuss the delirium-related distress was favored by both patients and relatives who had experienced postoperative delirium during previous hospital episodes. Finally, the lack of a control group is an

acknowledged limitation. While this was beyond the scope of this study, previous work has reported that symptoms of anxiety and depression are more prominent in patients following hematopoietic cell transplantation if they suffered from delirium once adjusting for potential confounders including disease severity, comorbidity, steroid usage, and pain.[11,12]

These findings are in keeping with similar studies in other patient populations especially those with cancer who experience delirium during hospitalisation.[5] However, the longer-term 1-year follow-up in the present study adds to our understanding of this issue. While numbers were small, predominantly due to death/attrition from study, the negative impact of delirium on the perception of distress appeared to persist at 12-month follow-up. This is relevant in terms of both necessary translation of results into clinical services and future research in this field. Delirium-related distress is already thought to result in higher rates of symptoms of depression and nonengagement in future treatments,[14,15] so potential interventions to modify this negative consequence of delirium should be developed and evaluated in the clinical setting. At present, no "delirium distress" intervention exists, but this should be a focus of future research in this field.

5 | CONCLUSION

This study has shown high levels of postoperative delirium-related distress in both elective and emergency surgical patients and their relatives who observed the delirium persisting at 12-month follow-up. Alongside, established efforts to reduce the incidence of delirium attempts should also be made to minimize the impact of this common condition. Such supportive interventions should be derived through robust research methodology and if effective administered clinically to both patients and their relatives or carers.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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6.4 Conclusions

This literature review and observational study prompted by the process of patient and public co-design, constitutes the first step in a programme of work to better understand and ultimately modify delirium related distress after surgery. The findings confirm the considerable distress associated with delirium both for patients and for their relatives. This work has prompted an ongoing mixed methods research programme to fully describe how an intervention to minimise the distress related to delirium should look involving co-production and evaluation from clinical and academic delirium experts in a modified Delphi forum and qualitative work exploring patient and relative views through semi-structured interviews and thematic analysis. The resultant intervention will then be evaluated in a research study and if successful translated into routine care.

Chapter 7 - Summary and overall discussion

7.0 Summary of this thesis

Increasing numbers of older people are undergoing surgical procedures and present unique challenges in terms of adverse clinician reported outcomes such as morbidity and mortality, patient related outcomes such as cognitive or functional deterioration and process measures such as length of stay and financial cost. Due to the risk factors for developing arterial vascular disease, the vascular surgical population, which to date has been inadequately studied in this context, present a particularly 'high risk' group for the development of such outcomes. The challenge of managing multimorbidity, geriatric syndromes and functional issues in the perioperative setting is a national issue with several reports advocating the structured involvement of geriatricians in the care of older surgical patients.

The established methodology, Comprehensive Geriatric Assessment, can be used to evaluate and optimise older patients with complicated health and social care needs and is evidence based within the general medical and community setting. Using the MRC guidance for evaluating multicomponent interventions, such as CGA, offered a robust framework to underpin the research programme presented in this thesis. Stakeholder engagement with patients, their relatives, clinicians and managerial staff was key to co-designing and co-producing all stages of the programme.

A systematic review and narrative synthesis concluded that employing CGA methodology in the perioperative period is likely to have a positive impact on postoperative outcomes in older patients undergoing elective surgery but that more

research was required. Following this a national survey was undertaken to establish whether such CGA based geriatrician led perioperative medicine services existed in UK NHS trusts. This reported that in 2014 only three trusts of 161 surveyed, employed CGA methodology throughout the perioperative pathway, with a further 12 trusts using CGA preoperatively and 26 trusts using CGA postoperatively.

Having established the need for ongoing research in this field an observational study was undertaken showing that cognitive impairment (measured using the MoCA) and frailty (measured by the EFS) are common in older vascular surgical patients and that the combined presence of these preoperative characteristics was predictive of a longer length of hospital stay in older vascular surgical patients.

A sample of 209 older elective vascular surgical patients were then randomised to receive either preoperative CGA and optimisation or standardised nurse led preoperative assessment using length of hospital stay as the primary outcome measure. The intervention group receiving preoperative CGA and optimisation had a 40% reduction in length of stay likely due to fewer observed medical issues such as postoperative delirium and postoperative cardiac complications.

Finally, the patient reported outcome of delirium distress was raised through the process of patient and public engagement as being of importance to service users. This resulted in a co-designed observational study which showed high levels of postoperative delirium-related distress (measured using a distress thermometer) in

both elective and emergency surgical patients and their relatives who observed the delirium.

7.1 This thesis in the context of other academic work

After the publication of the systematic review examining preoperative CGA in elective patients (chapter 2) but before the publication of the randomised control trial (chapter 5), a Cochrane review was published examining the impact of CGA on postoperative recovery in older people following surgery [75]. This paper included seven studies where participants had undergone emergency surgery for fractured hip and one trial in patients undergoing cancer surgery concluding that CGA probably reduces mortality, discharge to a more dependent level of care, length of hospital stay and total cost in those following hip fracture but with insufficient evidence to draw the same conclusion in other patient groups. This endorses the need to have conducted the study presented in chapter 5. Subsequent to this Cochrane review and our randomised controlled trial in vascular surgery (chapter 5), a randomised controlled study in patients undergoing colorectal cancer surgery has conversely reported that preoperative CGA is not effective in reducing postoperative complications (defined using Clavien Dindo score II-V) when compared to usual care [76]. However, the limitations of this research should be considered when interpreting and translating the reported conclusion into clinical practice. The study was underpowered due to funding issues but equally, if not more importantly, demonstrated suboptimal fidelity to the evidence based process of CGA. Furthermore the intervention was not multidisciplinary and the timeline between the CGA intervention and the surgical procedure was short which may have limited the efficacy of CGA in modifying the

primary and secondary outcomes. However, the publication of research such as this, since the papers presented in this thesis were published, is encouraging as a demonstration of the appetite to improve care for this vulnerable patient group. Other work using improvement science has also built on the findings from this thesis and begun the process of translating CGA and optimisation based perioperative care into routine clinical services. An example of this is described in a paper published in 2018 reporting similar outcomes to those seen in this thesis but using quality improvement methods [77].

7.2 This thesis in the context of national policy drivers

The growing body of published literature examining CGA and optimisation based services for older surgical patients has begun to influence the national agenda in this field. Building on the impetus of reports such as 'An Age Old Problem' released in 2010 and described in section 1.0, the annual reports from the National Emergency Laparotomy Audit (NELA) have further raised the profile of geriatric medicine CGA based input into pathways of care for older patients undergoing emergency surgery [78]. Although not yet realised, the hope is that through financial incentives linked to robust national data collection, geriatrician led, CGA based care will be delivered to all older surgical patients as the best practice tariff and National Hip Fracture Database has facilitated in orthogeriatrics [56].

In 2015 the Royal College of Anaesthetists (RCoA) released a statement setting out their vision for the development of perioperative medicine in the UK [79]. This vision involved a collaborative approach to perioperative care throughout the pathway with

resources appropriately focussed on the high risk patient using expertise at the correct stage of the patient journey with the meaningful use of data to minimise variation in standards of care nationally. Employing the expertise of geriatricians, allied health professionals and specialist nurses with clinical gerontology skills using CGA and optimisation based methodology fits with this national vision and reflects the observed uptake of this approach since this work began [80].

7.3 This thesis in the context of available methodology

This thesis illustrates the need to employ mixed research methods when investigating complex heterogeneous patient groups undergoing multicomponent interventions. First, underpinning this research programme with the MRC guidance for developing and evaluating complex interventions provided a structure to ensure that all necessary steps in the design and execution of the research were included. Second, the use of patient and public involvement in co-design enabled the measurement of outcomes which were pertinent to all stakeholders; clinicians, managers, patients and their relatives. Furthermore, co-designing practical aspects of the research studies resulted in rapid recruitment with minimal attrition due to specific methodology such as the novel approach of screening, consenting and randomising at the first meeting between patient participant and researcher. Third, skills were gained in systematic reviewing, narrative synthesis, survey methodology, observational cohort studies, feasibility work, conducting a randomised controlled trial and working within sections 30-34 of the Mental Capacity Act (2005) in gaining ethical approval to recruit patient participants who lack capacity to consent.

Limitations to the research findings include the inability to provide statistical power through meta-analysis following systematic review, inherent issues in survey research, use of dichotomised variables in the observational studies and the potential for limited external validity from a single site RCT. Whilst these limitations cannot be fully mitigated within the constraints of this PhD, the employment of mixed methods, stakeholder co-design and the underpinning MRC framework improved the quality of this research programme and the outputs, in addition to delivering invaluable experience in different research methods.

7.4 Translating and implementing the findings from this thesis and continuing the research programme

Since the completion of this research programme, work has been ongoing both locally and nationally to translate the conclusions into practical service changes. This translation process has involved collaboration with implementation scientists and is an ongoing programme of work addressing contextual and mechanistic factors in implementation of study findings.

To date the following changes have been effected; establishment of a patient and public liaison group to co-design and co-produce ongoing research studies and clinical service changes; substantive funding for a consultant geriatrician to deliver CGA and optimisation based care to older vascular surgical patients pre and postoperatively at the trust where the randomised controlled trial was conducted; a repeat of the national survey to examine the expansion of CGA based geriatrician led services since the 2014 survey [73]. This work is informing the process of collaborative grant writing

to scale up geriatrician led CGA based services nationally. Building on the delirium distress project presented in this thesis, a qualitative study describing what patients and relatives would want in an intervention to minimise delirium related distress, has been completed and is being submitted for publication. A modified Delphi process has been conducted with an expert panel to further develop a potential intervention with the aim of trialling this intervention in a future research study once grant funding is secured.

In summary this translatable mixed methods research programme has added to the existing literature by describing the cognitive and frailty burden in the older vascular surgical population and showing the positive impact that preoperative CGA and optimisation has in reducing the frequency of postoperative medical complications such as delirium thus resulting in a shorter length of hospital stay after elective arterial surgery. The provision of current CGA based services has been described at a national level in the UK. In addition, the significant distress related to postoperative delirium has been quantified using a distress thermometer highlighting the impact not only on patients but also on relatives. An ongoing research programme is continuing to further develop understanding in these fields.

Chapter 8 – Conclusions

[1] To describe the literature examining whether preoperative CGA affects postoperative outcomes in older patients undergoing scheduled (non emergency) surgery

Existing literature suggests that preoperative CGA and optimisation may improve postoperative outcomes in older patients undergoing elective surgery but more research is required

[2] To describe delivery of geriatrician-led CGA services for older surgical patients within the UK NHS and examine how services are funded

A national UK wide survey identified three trusts reporting CGA and optimisation based input throughout the perioperative pathway for older surgical patients.

[3] To describe the geriatrician perceived barriers to the development of CGA services for older surgical patients

Geriatricians cite funding and workforce issues as the barriers to developing geriatrician led CGA and optimisation based services for older surgical patients.

[4] To describe multimorbidity, cognitive impairment and frailty in patients aged over 60 years undergoing emergency and elective aortic and lower limb arterial procedures

Frailty and cognitive impairment are common in older vascular surgical pts

[5] To describe the association between cognitive impairment and frailty and postoperative outcomes (primarily length of hospital stay)

The combination of frailty and cognitive impairment contribute to postoperative morbidity including delirium resulting in a longer length of hospital stay

[6] To determine the clinical feasibility of assessing cognitive impairment and frailty using different assessment tools and methods (Montreal Cognitive Assessment, MoCA, Edmonton Frailty Scale, EFS, Timed up and go, TUG, gait velocity)

These brief assessment tools measuring cognitive impairment and frailty were acceptable to older surgical patient and feasible in the preoperative setting.

[*7] To examine whether preoperative CGA and optimisation reduces length of stay in older patients undergoing vascular surgery compared to standard preoperative assessment processes*

Preoperative CGA and optimisation reduced length of stay in older patients undergoing vascular surgery by 40% when compared with standard preoperative assessment processes. This was predominantly due to fewer medical complications with a trend towards fewer delayed discharges.

[8] To describe the distress related to an episode of postoperative delirium in older surgical patients and their relatives using the distress thermometer

The recollection of postoperative delirium was distressing for patients and their relatives with a median score of 8/10 recorded on the distress thermometer in both groups.

[9] To examine the association between degree of distress and features of delirium on the Delirium Rating Scale both on resolution of delirium and at 12 month follow up

Associations were observed between the severity of delirium and phenotypic features of the delirious episode (presence of delusions, agitation, disorientation) and the degree of distress. These same associations were seen in both patients who recalled the postoperative delirium and relatives who observed it.

[10] To examine the association between recall of delirium and features of delirium on the Delirium Rating Scale

Perceptual disturbance occurring as part of the postoperative delirium was the only phenotypic feature associated with recall of the episode.

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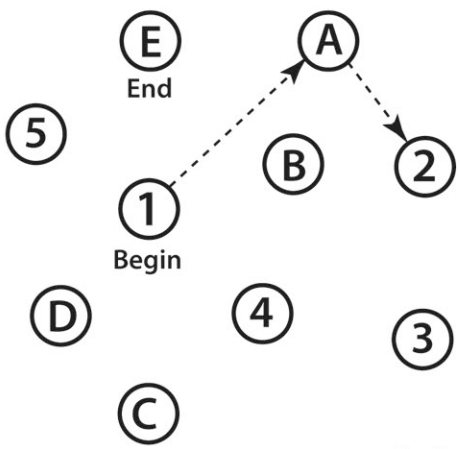
Appendices

MONTREAL COGNITIVE ASSESSMENT (MOCA)

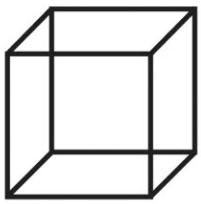
Version 7.1 Original Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE



[ ]



Copy cube

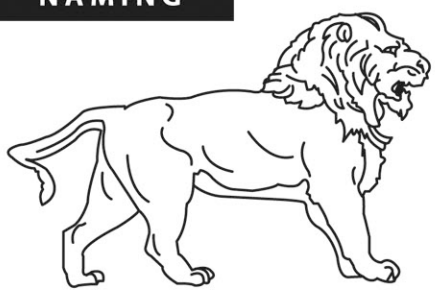
[ ]

Draw CLOCK (Ten past eleven)
(3 points)

[ ] Contour [ ] Numbers [ ] Hands

POINTS ___/5

NAMING



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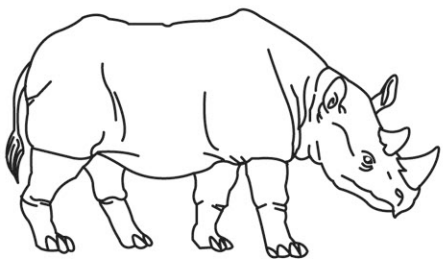

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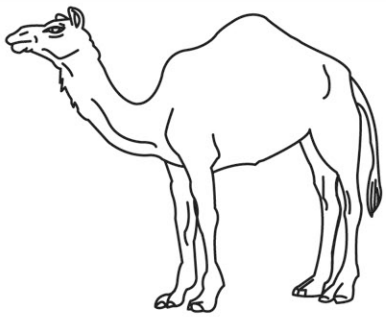

[ ]

___/3

MEMORY

Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION

Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

___/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

___/3

LANGUAGE

Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

___/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

___/1

ABSTRACTION

Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

___/2

DELAYED RECALL

Optional

	FACE	VELVET	CHURCH	DAISY	RED
Has to recall words **WITH NO CUE**	[ ]	[ ]	[ ]	[ ]	[ ]
Category cue					
Multiple choice cue					

Points for UNCUED recall only

___/5

ORIENTATION

[ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

___/6

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Normal ≥ 26 / 30

TOTAL ___/30

Add 1 point if ≤ 12 yr edu

Administered by: _____

Edmonton Frail Scale				Score: / 17
Frailty Domain	*Item*	*0 points*	*1 point*	*2 points*
Cognition	Clock drawing	No errors	Minor spacing errors	Other errors
General health status	In the past year, how many times have you been admitted to a hospital?	0	1-2	>2
	In general, how would you describe your health?	'Excellent' 'Very good' 'Good'	'Fair'	'Poor'
Functional independence	With how many of the following activities do you require help? (meal preparation, shopping, transportation, telephone, housekeeping, laundry, managing money, taking medications)	0-1	2-4	5-8
Social support	When you need help can you count on someone who is willing and able to meet your needs?	Always	Sometimes	Never
Medication use	Do you use five or more different prescription medications on a regular basis?	No	Yes	-
	At times, do you forget to take your prescription medications?	No	Yes	-
Nutrition	Have you recently lost weight such that your clothing has become looser?	No	Yes	-
Mood	Do you often feel sad or depressed?	No	Yes	-
Continence	Do you have a problem with losing control of urine when you don't want to?	No	Yes	-
Functional performance	Timed up and go	0-10 s	11-20s	>20 s Unwilling/unable
Total				

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REVIEW

Frailty in the older surgical patient: a review

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Abstract

The rate of surgical procedures in the older population is rising. Despite surgical, anaesthetic and medical advances, older surgical patients continue to suffer from adverse postoperative outcomes. Comorbidities and reduction in physiological reserve are consistently identified as major predictors of poor postoperative outcome in this population. Frailty can be defined as a lack of physiological reserve seen across multiple organ systems and is an independent predictor of mortality, morbidity and institutionalisation after surgery. Despite this identification of frailty as a significant predictor of adverse postoperative outcome, there is not yet a consensus on the definition of frailty or how best to assess and diagnose it. This review describes our current definitions of frailty and discusses the available methods of assessing frailty, the impact on the older surgical population and the emerging potential for modification of this important syndrome.

Keywords: *frailty, surgery, older adults, outcomes, interventions, elderly*

Introduction

Ageing of the surgical population

Over the last 20 years, the number of older people undergoing surgical procedures has increased faster than the rate of population ageing [1, 2]. This is likely to be related to changes in anaesthetic and surgical techniques, patient expectations and increasing evidence of improved morbidity and mortality following surgery even in the oldest old [3–6]. However, despite surgical and anaesthetic advances and improvements in the medical care of older surgical patients, adverse postoperative outcomes, particularly medical complications still remain commoner in older people when compared with their younger counterparts [7–11]. These complications are particularly significant as 30-day postoperative complications are more important than preoperative risk factors and intraoperative factors in determining survival after major surgery [7, 11]. There has been a focus on age and pre-existing comorbidities as the main predictors of adverse postoperative outcome in the older surgical population [7, 9, 12]. The role of frailty as an independent risk factor for adverse postoperative outcomes is now emerging [13, 14].

Why measure frailty in surgical patients?

Studies in various surgical populations have identified frailty as an independent risk factor for major morbidity, mortality, protracted length of stay (LOS) and institutional discharge [13–17]. Its importance is being recognised in influential reports such as the most recent National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report, 'An Age Old Problem' [18]. The authors of this report stated in the second of their principle recommendations that 'comorbidity, disability and frailty need to be clearly recognised as independent markers of risk in the elderly' [18]. Within the older surgical population the process of preoperative assessment provides an opportunity for proactive recognition of the frailty syndrome. The preoperative assessment process can be considered to serve two broad purposes. First, to risk stratify patients in order that health professionals, patients and their relatives or carers are fully informed of the inherent risks in undergoing a procedure. Second, in order that modifiable factors are proactively identified and optimised preoperatively, thus improving the patient's likelihood of a successful outcome.

The appeal of measuring frailty in a surgical population lies in its utility both as a tool for preoperative risk

stratification and also as a method for identifying potentially modifiable factors that can be optimised preoperatively.

Defining frailty

Frailty has been a concept in the clinical and research literature for two decades now. While most geriatricians can accurately identify a frail patient, a consensus regarding the definition has proved difficult to achieve [19–21]. This may stem from the need to encompass a complex and poorly understood syndrome in terms that are useful both to the clinician and to the researcher. In addition an overlap exists between frailty and other syndromes or issues seen commonly in an older person [22]. These include sarcopenia, cachexia, disability and comorbidity [23, 24]. The debate continues about whether frailty is a syndrome or a series of age-related risk factors predicting the likelihood of future adverse events [19, 25].

Broadly speaking, frailty can be thought of as a decreased physiological reserve across multiple organ systems [26]. Campbell defines frailty as 'a condition or syndrome which results from a multi-system reduction in reserve capacity to the extent that a number of physiological systems are close to, or past, the threshold of symptomatic clinical failure. As a consequence the frail person is at increased risk of disability and death from minor external stresses' [27]. The debate continues about the position frailty occupies on the spectrum between normal ageing at one end, and discreet pathophysiological entity at the other [19].

Models of frailty

Two main models of frailty exist: the frailty phenotype [28] and the frailty index or deficit accumulation model [29–32]. These models were derived from data taken from the Cardiovascular Health Study and the Canadian Study of Health and Aging, respectively [31, 33].

Frailty phenotype

The frailty phenotype proposes the relationship between a set of criteria that define frailty (unintentional weight loss, grip strength, self-reported exhaustion, gait speed, low physical activity level) and the effect on certain outcome measures (new falls, deteriorating mobility, disability, hospitalisation, death) [28].

Deficit accumulation model of frailty

The deficit accumulation model of frailty reflects the number of deficits an individual has accrued across a number of different domains [29, 30, 34]. These domains include current illnesses, ability to manage activities of daily living (ADL) and physical signs. This model allows for the calculation of a 'frailty index' which can be thought of as 'a count of an individual's accumulated deficits' [30, 34, 35].

The debate continues as to whether cognitive impairment, socio-demographic measures and affective disorders should be included in the definition of frailty. Furthermore, there is no consensus on whether frailty should be a clinical diagnosis or based on a combination of medical, functional and laboratory measures.

Measuring frailty

The lack of consensus on which method should be used to measure frailty is due to several issues [36]. First, the absence of a universally accepted definition hampers precise identification or measurement. Second, there are different intentions in measuring frailty; assessing, screening, case-finding or predicting prognosis. Third, measurement tools differ according to whether the tool is intended for the researcher, lay research assistant, geriatrician, general practitioner, public health physician, epidemiologist or allied health professional [25, 37]. Fourth, measurement of frailty has mainly been undertaken in the research setting and thus the assessment of clinically feasible tools is only just emerging in the literature.

Which tools do we have?

The measurement tools that exist are either scoring systems based on various aspects of physical, cognitive or functional capability [28, 30, 38–40] or are 'surrogate single measures' of frailty based on assessment of functional status [41–43]. These purely functional measures include forearm grip strength and gait speed. The majority of available tools have not been assessed according to their clinometric properties. A systematic review of frailty measurement tools recently concluded that while there are clearly advantages and disadvantages of all measurement tools, the most suitable tool for frailty research is the frailty index [30, 40].

Which tool to use clinically?

The question of the best clinical tool for assessment of frailty remains unanswered. Choosing a frailty assessment tool for the older surgical population should be undertaken in light of the two main purposes of preoperative identification of frailty: risk stratification and identification of factors for potential modification. For example, single surrogate measures such as grip strength have the benefit of simplicity, reproducibility and application to the busy preoperative setting and can define an individual as being 'at risk' of adverse postoperative outcomes [44]. Such measures do not point the clinician to clear areas for modification of frailty though. In contrast the Edmonton Frail Scale (EFS) or Reported Edmonton Frail Scale (REFS, in which the timed up and go assessment has been replaced by reported physical functioning) can also effectively risk stratify but may better highlight aspects of frailty that are amenable to preoperative optimisation [13, 38, 45]. These may include

preoperative medication review, treatment of depression, cognitive screening or pre-emptive provision of social support. The EFS has been validated for use among non-geriatricians and assesses multiple domains in less than 5 min [38]. At the opposite end of the spectrum the Comprehensive Assessment of Frailty (CAF) score, developed according to the Fried criteria to assess frailty in the context of cardiac surgery, is complex and cardiac specific (including measures such as brain natriuretic peptide level and ejection fraction) [15]. While this may be useful in the research setting, it is difficult to see how measures such as this could be easily applied in a clinical context.

American studies have used variables associated with frailty, rather than a specific validated frailty score [46, 47]. This method is not in keeping with the current emphasis on accurately defining frailty and other complex geriatric syndromes (such as sarcopenia) [20, 23, 25]. Furthermore, unless an accepted definition or assessment method is used in such studies, the applicability of the findings may be limited.

Frailty and surgery

Prevalence of frailty in the older surgical population

The prevalence of frailty in patients of all ages presenting for surgical procedures is quoted at between 4.1 and 50.3% [14–17]. This wide variation relates to the issues of definition, measurement and varying populations studied. A recent UK study used the Fried model to define frailty in community-dwelling people aged between 65 and 74 years [48]. Prevalence rates of frailty in this study were 8.5% for women and 4.1% for men. Studies examining older patients undergoing elective cardiac and non-cardiac surgery quote prevalence rates of frailty at between 41.8 and 50.3% [14–16]. This high prevalence of frailty in older surgical populations, compared with the prevalence rate of less than 10% observed in older community-dwelling individuals, highlights the vulnerability of this patient group.

Impact of frailty on surgical outcomes

Table 1 summarises the impact of frailty across different surgical populations. The table illustrates the relative paucity of research and the disparate approach to the measurement of frailty.

Notably the two studies by Robinson *et al.* (Table 1) show a very high incidence of post-discharge institutionalisation (26 and 30%, respectively) [46, 47]. While the high rate of institutionalisation may reflect a difference in the American social care model, the findings of these studies raise two questions. First, was it appropriate to perform surgery in this group with over a quarter subsequently needing institutional care? Second, what is the role for intervention targeted at individual components of the frailty syndrome in improving surgical outcomes?

Inflammatory biomarkers and postoperative outcomes

A recent study examined inflammatory biomarkers, thought to be important in the pathophysiology of frailty, and the association with postoperative complications in older colorectal surgical patients [49]. Patients aged 70 years or over were defined as frail, pre-frail or robust using comprehensive geriatric assessment (CGA) and an approximation to the frailty phenotype. The inflammatory biomarkers C-reactive protein (CRP), interleukin-6 (Il-6), tumour necrosis factor-α (TNF-α) and D-dimer were examined 2 weeks prior to elective resection for colorectal cancer. Levels of CRP, Il-6 and TNF-α increased significantly with increasing frailty level. Having adjusted for tumour location, which is an established risk factor for postoperative complications, both CGA defined frailty and Il-6 were predictive of complications.

Can the syndrome of frailty be modified?

The interaction of frailty with other geriatric syndromes

Figure 1 shows the overlap between frailty and other geriatric syndromes.

The aetiology of these conditions is incompletely understood but involves some common processes [23, 50–53]. Certainly the dysregulation of inflammatory pathways seems to be important in the pathophysiology of frailty [54]. Several biomarkers and combinations of biomarkers have been suggested as measures of frailty. These include CRP, albumin, Il-6 and TNF-α [52, 55, 56]. This overlap in the pathophysiology of geriatric syndromes may be relevant in the development of future modifications.

Progression of the frailty syndrome

Transition from one frailty state to another has a resultant impact upon mortality [57]. The natural history of frailty shows that it is more common to progress to a state of greater frailty than to improve to a state of lesser frailty [57]. However, even without intervention, some individuals become 'less frail'. These observed transitions between different 'degrees of frailty' suggest that potential interventions aimed at lessening the state of frailty may well be effective.

Using exercise to modify frailty

Spontaneous increase in gait speed over a 12-month period in community-dwelling over 65 year olds predicted an improved 8-year survival [58]. This raises the question of whether targeted interventions to improve gait speed would have similar effects reducing frailty and improving mortality and outcomes after surgery. Individual and group exercise programmes have been shown to improve mobility and ADL in the long-term care population many of whom are frail [59]. Contradictory evidence exists regarding the role

Table 1.

Method of measuring frailty	Impact of frailty on surgical outcome	Surgical population studied	Authors and reference
Grip strength	Increased postoperative complications Increased LOS	All ages Elective major abdominal surgery	Klidjian *et al.*[44]
Gait speed	Composite endpoint of in-hospital postoperative mortality or major morbidity (as defined by Society of Thoracic Surgeons criteria) Cardiac surgery	≥70 years old	Afilalo *et al.*[16]`
Edmonton Frail Scale	Postoperative complications Prolonged LOS Increased institutionalisation rate	≥70 years old Lower limb orthopaedic surgery Spinal surgery Abdominal surgery Vascular surgery	Dasgupta *et al.*[13]
Frailty score based on frailty phenotype	Postoperative complications Prolonged LOS New institutionalisation at discharge	≥65 years old Elective surgery (major and minor)	Makary *et al.*[14]
Comprehensive Assessment of Frailty Score	Increase in 30-day mortality	Cardiac surgery	Sundermann *et al.*[15]
8 'markers' of frailty (age, cognition, recent weight loss, BMI, serum albumin, falls, depression, haematocrit)	Increase in 6-month mortality (although underpowered for this) Post-discharge institutionalisation	≥65 years old General, thoracic, urology and vascular surgery (patients undergoing major elective surgery necessitating postoperative surgical ICU admission)	Robinson *et al.*[46]
14 frailty 'characteristics' in 6 domains (comorbidity, function, cognition, geriatric syndromes, extrinsic frailty) NB: most closely associated were TUAG ≥ 15 seconds and functional dependence	Institutionalisation at hospital discharge	≥ 65 years old Elective general, cardiac, thoracic, urology and vascular surgery (patients undergoing major elective surgery necessitating postoperative surgical ICU admission)	Robinson *et al.*[47]
Frailty defined as any impairment in activities of daily living (Katz index) or impairment of ambulation or diagnosis of dementia	In-hospital mortality Institutional discharge Mid-term survival	All ages Cardiac surgery	Lee *et al.*[17]
Groningen frailty indicator	Post-operative delirium	All ages Elective vascular surgery	Pol *et al.*[86]

of different forms of exercise training [60–62]. The effect of such training on survival or other postoperative outcomes within the older frail surgical population has not been evaluated.

Studies of exercise training in heart failure have shown improvement in symptoms and exercise capacity in addition to favourable changes in skeletal myopathy, endothelial function and cytokine expression [63]. Although not directly comparable with the frail population, the underlying cytokine mechanisms behind these syndromes may overlap, given the role of TNF in the 'cardiac cachexia' of chronic heart failure. The benefit and tolerability of exercise programmes tailored specifically for older frail patients with heart failure should pave the way for research into the potential therapeutic role of exercise training within the frail surgical population [64, 65]. A Cochrane review has found a positive link between progressive resistance training and strength and function, but the role of power versus strength training and the longitudinal view of exercise in modifying sarcopenia and frailty is still unclear [66].

Using nutrition to modify frailty

Although the anaemia associated with frailty is likely to be related, at least in part, to inflammatory changes associated with the syndrome, within the older population anaemia can also be considered a surrogate marker of nutrition. The role of treating anaemia preoperatively in elective orthopaedic patients is now accepted as a method of reducing morbidity and mortality in this older surgical group [67]. Current recommendations suggest replacing iron, vitamin B12 and folate at least 28 days before scheduled elective surgery [67]. The impact of improving other nutritional deficiencies on the severity of frailty is less well understood. Despite the association observed between 25-hydroxyvitamin D and frailty [56], nutritional supplementation (multi-nutrient supplementation and vitamin D) in combination with physical activity intervention does not seem to independently improve the function of frail older people [61, 68]. Considering the overlapping geriatric syndrome of sarcopenia, evidence from a recent systematic review suggests that vitamin D supplementation may be

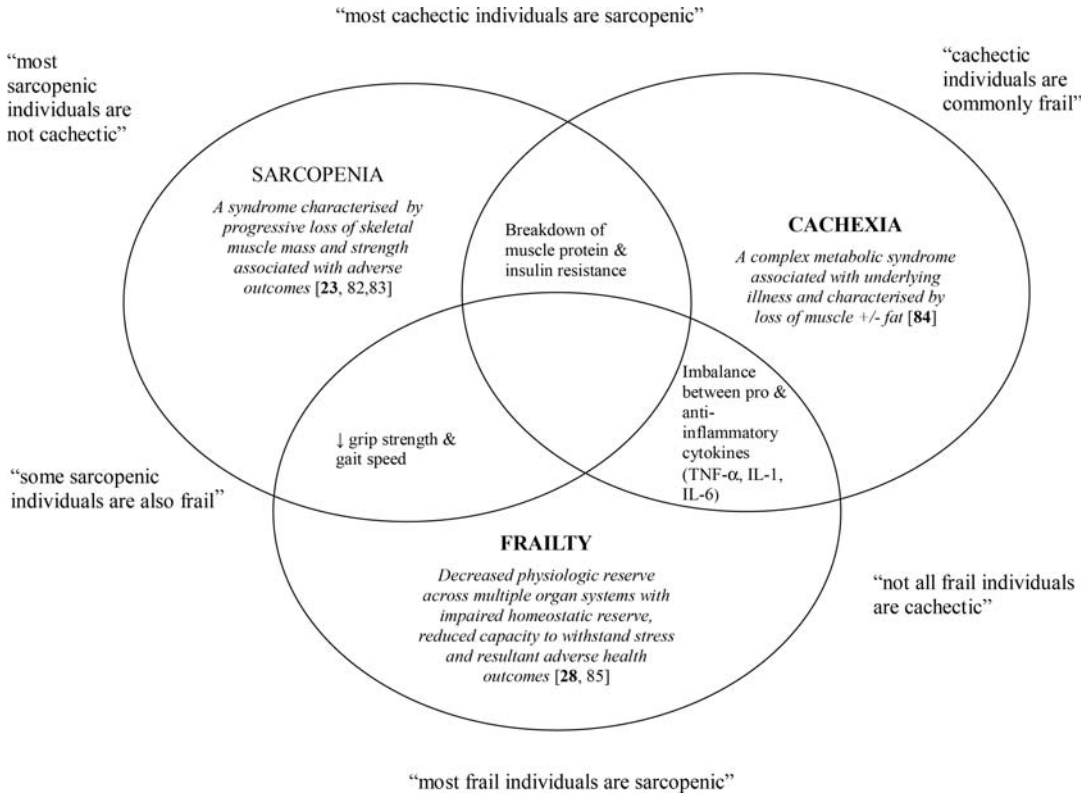

Figure 1. Overlapping geriatric syndromes.

indicated to combat sarcopenia in those with low vitamin D levels [69]. The role of nutritional intake may play a part in the development of sarcopenia and evidence supports the potential role of increased protein intake as a therapeutic intervention in targeting sarcopenia. Controversy exists regarding the amount of protein supplementation and the manner in which this should be taken [70, 71]. With a move towards promoting nutrition as part of enhanced recovery programmes in colorectal surgery [72–74], the potential effect that nutritional supplementation may have on surgical outcomes in frail individuals should be explored.

Using drug therapies to modify frailty

At present there is no consensus regarding the potential pharmacological modification of frailty or related geriatric syndromes [75]. Potential modulators of frailty include anabolic steroids, growth hormone and anticytokine agents [53]. Other strategies have been employed in sarcopenic patients with varying degrees of benefit. Testosterone and growth hormone are not currently recommended in sarcopenia due to lack of efficacy and unacceptable side-effect profiles and more work is needed on antioxidants and creatine [70]. However, a randomised controlled trial has shown that improved exercise capacity and fewer falls were seen in older patients with impairment in ADL, given angiotensin-converting enzyme (ACE) inhibitors, and this has attracted interest in the potential role of ACE inhibitors in preventing or reducing the progression of sarcopenia [76]. The mechanisms by which ACE inhibitors may have an effect on sarcopenia or body composition are not understood [70].

The impact of other factors on modifying frailty

A positive affect has been shown to significantly lower the risk of becoming frail [77]. Depression is an independent correlate of frailty in community-dwelling older people [78]. The role of treating depression, on reducing the implications of frailty within the older surgical population, remains less clear. Frailty has been shown to be independently associated with individual and neighbourhood socioeconomic factors [79]. This implies that policies targeting frailty in older adults may need to incorporate the wider social context of frailty.

Unanswered questions and future research

In summary, frailty is predictive of mortality, postoperative complications and institutional discharge in older patients undergoing cardiac and non-cardiac surgery. The evidence suggests that aspects of frailty may be amenable to intervention that could potentially reduce adverse outcomes. In the surgical population this raises numerous questions that are currently unanswered by the literature:

- Should we routinely measure frailty in the preoperative older patient?

- Which tool, biomarker or functional assessment would be most clinically applicable?
- Who should be measuring this?
- Is the measurement of frailty most useful in predicting surgical risk or in identifying issues for modification and optimisation?
- What should our 'frailty intervention' be?
- When should the intervention be employed with respect to the timing of surgery?
- What about emergency surgery?
- How about cancer surgery?
- Do interventions positively impact adverse postoperative outcomes?

Research into frailty is needed to answer these questions. Future work should be directed at refining diagnostic and screening tools, better understanding the epidemiology and natural history of frailty and understanding the potential for intervention both in terms of inflammatory modulation [53] and clinical intervention [25, 37, 80, 81]. This potential for proactive intervention and modification of the features of frailty may positively impact surgical outcomes in older patients in the future [82–86].

Key points

- An increasing number of frail older patients are undergoing surgical procedures.
- Frailty is an independent risk factor for adverse postoperative outcomes.
- The evidence that aspects of frailty can be modified is emerging.
- Optimisation of frail older patients prior to surgical procedures could improve postoperative outcomes.

Supplementary data

Supplementary data mentioned in the text is available to subscribers in *Age and Ageing* online.

References

PLEASE NOTE: The long list of references supporting this review has meant that only the most important are listed here and are represented by bold type throughout the text. The full list of references is available as Supplementary data are available in *Age and Ageing online*, Appendix 1

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<p>Perioperative medicine for older surgical patients; a UK survey</

***1. Does the hospital where you work have structured geriatric medicine input into the care of older surgical patients?**

- Yes
- No

***2. THE PREOPERATIVE PHASE**

Does the hospital where you work have geriatric medicine delivered preoperative services for older surgical patients?

- Yes
- No

*3. THE PREOPERATIVE PHASE

Is the preoperative geriatric service delivered to?

- [ ] Elective surgical patients
- [ ] Emergency surgical patients

*4. How is perioperative risk assessed by the geriatric medicine team in the preoperative setting?

- [ ] No risk assessment
- [ ] Assessment of comorbidities
- [ ] Comprehensive Geriatric Assessment
- [ ] Measures of frailty
- [ ] American Society of Anesthesiologists Score (ASA)
- [ ] POSSUM

Other (please specify)

*5. THE PREOPERATIVE PHASE

How are older surgical patients preoperatively optimised by the geriatric medicine team?

- ○ No optimisation (e.g., referred back to GP, organ specific physician, anaesthetists)
- ○ Optimisation delivered by consultant geriatrician
- ○ Optimisation delivered by geriatrician led MDT

Other (please describe)

*6. Is your geriatric medicine team asked to assess capacity for consent in older surgical patients?

- ○ Yes
- ○ No

If yes, how many times in the last month?

***7. At your hospital do the geriatric medicine team have input into the development of perioperative guidelines e.g. cessation of antiplatelets, postoperative delirium etc?**

- Yes
- No

If yes please describe your involvement and the topic of the guideline

***8. THE POSTOPERATIVE PHASE**

Does the hospital where you work have structured geriatric medicine input into the postoperative care of older surgical patents?

- Yes
- No

Any comments

*9. THE POSTOPERATIVE PHASE

Is the postoperative geriatric medicine service delivered to patients undergoing?

- [ ] Elective surgery
- [ ] Emergency surgery

Other (please specify)

*10. THE POSTOPERATIVE PHASE

How is postoperative geriatric medicine liaison delivered in the hospital where you work?

	Yes	No
Reactive ward liaison i.e. geriatric team receive referrals from surgical teams for medical advice, discharge planning, capacity assessment etc	○	○
Proactive case finding i.e. geriatricians instigate ward rounds, MDTMs, discharge planning etc	○	○

Other (please describe)

11. THE POSTOPERATIVE PHASE

If you deliver a postoperative service (reactive, proactive or a combination of both) then please describe the key features below

***12. Think back to the last surgical patient you saw. Please indicate why you were involved in their care. Please mark all that apply.**

- [ ] Preoperative medical management
- [ ] Assessment of capacity (e.g., for consent or for discharge destination planning)
- [ ] Postoperative medical management
- [ ] Rehabilitation and goal setting
- [ ] Discharge planning
- [ ] Setting ceilings of care
- [ ] Sanctioning a move to a geriatric medicine bed
- [ ] Sanctioning a move to a community rehabilitation facility

Other (please specify)

***13. ORGANISATIONAL INFORMATION**

In the last 12 months how many times have you or the geriatric medicine team you lead presented at local hospital audit meetings in?
(Please exclude geriatric or medicine audit meetings where there is no surgical or anaesthetic presence)

	0	1	2	3	>3
Surgery	○	○	○	○	○
Anaesthetics	○	○	○	○	○

Please describe

***14. ORGANISATIONAL INFORMATION**

Would you like to further develop geriatric medicine provision to older surgical patients within your hospital?

- ○ Yes
- ○ No

*15. ORGANISATIONAL INFORMATION

What would help you to develop the geriatric medicine provision to older surgical patients in your hospital? Please rank these in order of importance (1 being most important)

☐	Allocated consultant geriatrician sessions
☐	Allocated junior doctor sessions
☐	Allocated clinical nurse specialist time
☐	Allocated allied health professional time
☐	Clinical guidelines covering common perioperative scenarios
☐	Education/training in perioperative medicine for older patients
☐	'Buy-in' from consultant surgeons
☐	'Buy-in' from consultant anaesthetists
☐	'Buy-in' from managers
☐	'Buy-in' from commissioners
☐	Advice writing a business case
☐	Other (please elaborate in question 19 if you wish)

*16. ORGANISATIONAL INFORMATION

Do you have dedicated funded sessions for geriatric surgical liaison in your hospital? If so how is this funding allocated?

	Yes	No
No dedicated funded sessions	○	○
Consultant geriatrician	○	○
Geriatric medicine SpR	○	○
Geriatric medicine FY2/SHO/Trust Dr	○	○
Clinical Nurse Specialist	○	○
Physiotherapist	○	○
Occupational therapist	○	○
Social worker	○	○
Administrator	○	○

Other (please specify)

*17. ORGANISATIONAL INFORMATION

Who funds the geriatric medicine input into the care of older surgical patients in your hospital?

- ○ Not applicable
- ○ Medical directorate
- ○ Surgical directorate
- ○ Combined medical and surgical directorate
- ○ Absorbed into existing geriatric services without specific funding

Other (please specify)

*18. ORGANISATIONAL INFORMATION

Does the hospital where you work perform?

	Yes	No
Emergency surgery	○	○
Elective surgery	○	○

Other (please specify)

19. THANK YOU FOR COMPLETING THIS SURVEY

If you would like to say anything else about geriatric medicine input into the care of older surgical patients please comment below.

PARTICIPANT INFORMATION SHEET – Patients

Study Title: Outcomes in older patients undergoing vascular surgery

1. Outline explanation

All patients aged over 65 who are having certain operations at St Thomas' Hospital are being invited to take part in a research study. If you choose to take part you will be asked to complete several questionnaires with the help of a researcher. Before you decide whether you would like to take part please read this leaflet. It explains why we are doing the study and what it will involve. You can ask us any questions you wish about the study. You do not have to take part. It will not affect your care if you choose not to be a part of the research.

2. What is the purpose of the study?

We are collecting information about how surgery can affect older patients. We will look at how different medical problems can affect people's outcomes after operations. In particular we will look at how having an operation can affect the way you concentrate and think for a short while afterwards. By collecting this information we hope to design a service which will improve outcomes for older surgical patients.

3. Why have I been invited?

All patients age 65 and over having similar operations to you have been invited to take part in the study.

4. What will happen to me if I take part?

If you choose to take part in the study, a researcher (who is also a doctor within the NHS), will help you complete some questionnaires. These questionnaires have been tested in other studies and are called the Montreal Cognitive Assessment, Edmonton Frail Scale, Delirium Rating Scale, Barthel score, Hospital Anxiety and Depression Score and Mini Mental State Examination. The questions are about your memory, your mood and how you manage at home. Lots of these questions will be very straightforward for you but everybody in the study is being asked the same things. You will be asked to complete some of the questionnaires at 2 points during your stay in hospital. We will also ask you to complete some of the questionnaires for a final time when you come back to see the surgeon at your follow up clinic appointment. This will be the end of your participation in the study. We will need to look at your hospital records to complete our assessments. Whilst you are on the ward a physiotherapist will also assess how well you can walk (if you are able). We will measure how strong your hand grip is using a machine called a dynamometer.

5. Do I have to take part?

It is entirely up to you whether you choose to be a part of the study or not. It will not affect your care at all whether you choose to take part or not. If you do decide to take part we will ask you to sign a consent form. You are free to withdraw from the study at any time. The process of consenting to take part in this study is different from the process of consent for your operation. The researcher does not have anything to do with the process of consent for the operation.

6. What is the drug or procedure that is being tested?

There is no drug or procedure being used as part of this study. Instead it is an observational study which means that we only observe what is happening.

7. What are the possible disadvantages and risks of taking part?

There is no risk to you in taking part in the study. Your only direct involvement will be helping to complete the questionnaires. Your care will not be affected at all whether you choose to take part or not.

8. What are the possible benefits of taking part?

The information collected in the study will be used to help improve the outcomes of people like you having operations in the future.

9. What if new information becomes available?

Sometimes during the course of a research project new information becomes available about a drug or treatment that is being tested. This will not affect this study because we are just observing what happens. We are not going to give you any treatments that are different from usual.

10. What happens when the research study stops?

When the research project stops your usual care continues just as it has throughout the study.

11. What if something goes wrong?

We are not changing your treatment at all so you are not at any risk of harm as a result of taking part in the project. If you have a concern about any aspect of this study you should speak to the researcher who will do their best to answer your questions. However if you wish to complain about the way you have been treated as part of the study, the usual NHS complaints service is available to you (Patient Advice and Liaison Service, Guy's and St Thomas' Hospital, 02071883416).

12. Is the study confidential?

All the data we collect from the questionnaires and from your medical notes is confidential. We will not use your name or other information that could identify you.

13. What will happen to the results of the research study?

The results of the study will be presented to other health professionals at meetings and through publishing articles in journals. We will use the results to design a service which will help older people having operations in the future. You will not be identified in any report or publications. Sometimes when we write reports we include quotations that patients have given us as part of the study. If we use quotations they are always fully anonymised. If you are interested in the results of the study once it has finished you can contact the researcher who can give you a lay summary of the results. You can use the contact details below to do this if you wish to. This study will form part of a PhD.

14. Who is in charge of the research and how is it funded?

The research has been funded by Guy's and St Thomas' Charity. The researcher and supervisors are NHS doctors specialising in the healthcare of older people.

15. Who has reviewed the study?

The study has been reviewed by the Kings Health Partners Gerontology Clinical Academic Group and by the NHS Research Ethics Committee.

16. Contact details

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Email: judith.partridge@gstt.nhs.uk

Guy's and St Thomas' NHS
NHS Foundation Trust

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM - PARTICIPANTS

Title of Project: Outcomes in older patients undergoing vascular surgery

Name of Researcher: Judith Partridge

Please initial box

1. I confirm that I have read and understand the information sheet dated 25.02.11 (version 1.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from Kings College London, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the study ☐

---------- ---------- ----------
Name of participant Date Signature

---------- ---------- ----------
Name of person taking consent Date Signature

PARTICIPANT INFORMATION SHEET – Consultee

Study Title: Outcomes in older patients undergoing vascular surgery

1. Outline explanation

All patients aged over 65 who are having certain operations at St Thomas' Hospital are being invited to take part in a research study. If they take part they will be asked to complete several questionnaires with the help of a researcher.

You have been contacted to help us understand whether the patient would wish to participate. At the moment we do not feel that the patient can fully absorb all the information necessary to make a decision about being in the study. This leaflet explains why we are doing the study and what it will involve. You can ask us any questions you wish about the study. They do not have to take part. It will not affect their care if they are not a part of the research.

2. What is the purpose of the study?

We are collecting information about how surgery can affect older patients. We will look at how different medical problems can affect people having operations. In particular we will look at how having an operation can affect the way you concentrate and think for a short while afterwards. By collecting this information we hope to design a service which will improve outcomes for older surgical patients.

3. Why has my relative / friend been invited?

All patients age 65 and over having similar operations to your relative / friend have been invited to take part in the study.

4. What will happen to my relative / friend if they take part?

If they take part in the study, a researcher (who is also a doctor within the NHS), will help them complete some questionnaires. These questionnaires have been tested in other studies and are called the Montreal Cognitive Assessment, Edmonton Frail Scale, Delirium Rating Scale, Barthel Score, Hospital Anxiety and Depression Score and Mini Mental State Examination. The questions are about their memory, mood and how they manage at home. Lots of these questions will be very straightforward for them but everybody in the study is being asked the same things. They will be asked to complete some of the questionnaires twice during their stay in hospital. We will ask them to complete some of the questionnaires for a final time when they come back to see the surgeon at the follow up clinic appointment. This will be the end of their participation in the study. We will need to look at their hospital records to complete our assessments. Whilst they are on the ward a physiotherapist will also assess how well they can walk (if they are able). We will measure how strong their hand grip is using a machine called a dynamometer.

5. Does my relative / friend have to take part?

It is entirely up to you whether you think your relative / friend would wish to be a part of the study or not. It will not affect their care at all whether they take part or not. If you decide that they would wish to be included we will ask you to sign a consent form. Signing the consent form says that you think your relative / friend would want to be included in the study if they were able to answer for themselves. They are free to withdraw from the study at any time. You will not be asked to consent for any type of treatment on behalf of your relative / friend. The process of consenting to take part in this study is different from the process of consent for the operation. The researcher does not have anything to do with the process of consent for the operation.

6. What is the drug or procedure that is being tested?

There is no drug or procedure being used as part of this study. Instead it is an observational study which means that we only observe what is happening.

7. What are the possible disadvantages and risks of taking part?

There is no risk to your relative / friend in taking part in the study. Their only direct involvement will be helping to complete the questionnaires. Their care will not be affected at all whether they take part or not.

8. What are the possible benefits of taking part?

The information collected in the study will be used to help improve the outcomes of people like your relative / friend having operations in the future.

9. What if new information becomes available?

Sometimes during the course of a research project new information becomes available about a drug or treatment that is being tested. This will not affect this study because we are just observing what happens. We are not going to give any treatments that are different from usual.

10. What happens when the research study stops?

When the research project stops usual care continues just as it has throughout the study.

11. What if something goes wrong?

Because we are not changing any treatment at all your relative / friend is not at any risk of harm as a result of taking part in the project. If you or the participant has a concern about any aspect of this study you should speak to the researcher who will do their best to answer your questions. However if you or they wish to complain about the way they have been treated as part of the study, the usual NHS complaints service

is available to you (Patient Advice and Liaison Service, Guy's and St Thomas' Hospital, 02071883416).

12. Is the study confidential?

All the data we collect from the questionnaires and from the medical notes is confidential. We will not use their name (or your name) or other information that could identify you or the patient.

13. What will happen to the results of the research study?

The results of the study will be presented to other health professionals at meetings and through publishing articles in journals. We will use the results to design a service which will help older people having operations in the future. They will not be identified in any report or publications. Sometimes when we write reports we include quotations that patients have given us as part of the study. If we use quotations they are always fully anonymised. If you or your relative / friend are interested in the results of the study once it has finished you can contact the researcher who can give you a summary of the results. You can use the contact details below to do this if you wish to. This study will form part of a PhD.

14. Who is in charge of the research and how is it funded?

The research has been funded by the Guy's and St Thomas' Charity. The researcher and supervisors are NHS doctors specialising in the healthcare of older people.

15. Who has reviewed the study?

The study has been reviewed by the Kings Health Partners Gerontology Clinical Academic Group and by the NHS Research Ethics Committee.

16. Contact details

Judith Partridge
9th Floor North Wing
St Thomas' Hospital
Westminster Bridge Road
London
SE1 7EH

Tel: 0207 188 9916
Email: judith.partridge@gstt.nhs.uk

Guy's and St Thomas' NHS
NHS Foundation Trust

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM - CONSULTEES

Title of Project: Improving postoperative outcomes in older vascular surgical patients

Name of Researcher: Judith Partridge

Please initial box

1. I confirm that I have read and understand the information sheet dated 1.8.12 (version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that participation is voluntary and that the participant is free to withdraw at any time without giving reason, and without their medical care or legal rights being affected. ☐

3. I understand that relevant sections of the participant's medical notes and data collected during the study may be looked at by individuals from Kings College London, from regulatory authorities or from the NHS Trust, where it is relevant to their taking part in this research. I give permission for these individuals to have access to these records. ☐

4. I agree that the participant can take part in the study ☐

Name of participant

---------- ---------- ----------
Name of consultee Date Signature

---------- ---------- ----------
Name of person taking consent Date Signature

PARTICIPANT INFORMATION SHEET – Patients

Study Title: Evaluating the impact of preoperative Comprehensive Geriatric Assessment (CGA) to improve postoperative outcomes in older vascular surgical patients

1. Outline explanation

All patients aged over 65 who are having certain operations at St Thomas' Hospital are being invited to take part in a research study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it will involve. This leaflet explains why we are doing the study and what it involves. You can ask us any questions you wish about the study. You do not have to take part. It will not affect your care if you choose not to be a part of the study.

2. What is the purpose of the study?

The purpose of this study is to test our theory that care for older patients after surgery can be improved by seeing a healthcare team who specialise in preparing patients for surgery. We will look at how different medical problems can affect people's outcomes after an operation. In particular we will look at how having an operation can affect the way you concentrate and think after surgery. By assessing and treating medical conditions we hope to help you to recover and get back home again as quickly as possible. If you agree to take part in the study you will be put into one of two groups;

One group (the treatment group) will be given a thorough assessment by a healthcare team specialising in preparing older people for surgery (the POPS team). This usually involves a single visit only to a hospital clinic. The team consists of doctors, nurses, occupational therapists and social workers.

The other group (the control group) will be treated in the usual manner, which is routine care from a nurse in preassessment clinic possibly involving your GP and other services too. This also usually only involves a single visit to a different hospital clinic.

At the moment we only know that the new treatment is as good as the normal treatment in people having this type of surgery. We do not know if it is better. That is why we are going to offer half of the patients the new treatment and half of the patients' current treatment. We will then compare the results. So that we don't influence the results we will put patients into the treatment group or the control group randomly. This is like tossing a coin to decide which group you go into. It means that neither we nor you choose your treatment. No experimental medicines will be used in either group. Your operation will not be affected at all by taking part in the study.

3. Why have I been invited?

All patients age 65 and over having similar operations to you have been invited to take part in the study.

4. Do I have to take part?

It is entirely up to you whether you choose to be a part of the study or not. It will not affect your care at all whether you choose to take part or not. If you do decide to take part we will ask you to sign a consent form. You are free to withdraw from the study at any time. The process of consenting to take part in this study is different from the process of consent for your operation. The researcher does not have anything to do with the process of consent for the operation.

5. What will happen to me if I take part?

If you would like to take part you will be asked to sign a consent form. You are still free to change your mind about being in the study at any point. You will be invited to attend one of two clinics; either the POPS clinic held at the Older Person's Assessment Unit at Guy's Hospital or the usual preassessment clinic held at St Thomas' Hospital. You will then attend the hospital for your operation in the usual way. Researchers will collect information during these visits on your medical history, medications and time spent in hospital. All information will be kept anonymously.

5. What is the drug or procedure that is being tested?

We are testing a different way of working or a 'process of care' tailored towards older patients having operations. The study is designed so that patients will not be inconvenienced by taking part in it (for example we do not ask you to attend the hospital more times than you would anyway).

There is no drug being used as part of this study. As part of the assessment and treatment during the clinic your medicines may be changed. This will be at the advice of a doctor used to prescribing these medications. We will always inform your GP of any changes to your treatment. All medications are in routine usage and we are not testing any experimental drugs.

6. What are the possible disadvantages and risks of taking part?

There are no specific risks or disadvantages to you in taking part in the study. Your care will not be affected at all whether you choose to take part or not.

7. What are the possible benefits of taking part?

There may be benefits in having medical conditions identified and treated (for example, anaemia, high blood pressure etc). This may happen in either the treatment or control group. The information collected in the study will be used to help improve the outcomes of people like you having operations in the future.

8. What if new information becomes available?

Sometimes during the course of a research project new information becomes available about a drug or treatment that is being tested. This does not really apply to this study because we are testing a health care approach rather than a specific treatment or medicine.

9. What happens when the research study stops?

When the research project stops your usual care will continue. We will telephone you 3 months after your discharge from hospital in order to ask you 6 brief questions which relate to your quality of life. These questions will help us to calculate whether the clinic being tested in the study is good value for money. You will not be contacted again after this point.

10. What if something goes wrong?

If you are harmed by taking part in the research project there are no special compensation arrangements. If you are harmed due to someone's negligence then you may have grounds for legal action but you may have to pay for it. If you have a concern about any aspect of this study you should speak to the researcher who will do their best to answer your questions. However if you wish to complain about the way you have been treated as part of the study, the usual NHS complaints service is available to you (Patient Advice and Liaison Service, Guy's and St Thomas' Hospital, 02071883416).

11. Is the study confidential?

All the data we collect from you and your medical notes is confidential. We will not use your name or other information that could identify you when the results are analysed. As part of good practice we will communicate with your GP, surgeon and other doctors, nurses and therapists treating you just as we usually do. If, as part of the study, a participant raises concerns about abuse the researchers will alert the relevant authorities.

12. What will happen to the results of the research study?

The results of the study will be presented to other health professionals at meetings and through publishing articles in journals. You will not be identified in any report or publications. Sometimes when we write reports we include quotations that patients have given us as part of the study. If we use quotations they are always fully anonymised. If you are interested in the results of the study once it has finished you can contact the researcher who can give you a lay summary of the results. You can use the contact details below to do this if you wish to. This study will form part of a PhD.

13. Who is in charge of the research and how is it funded?

The research has been funded by Guy's and St Thomas' Charity. The researcher and supervisors are NHS doctors specialising in the healthcare of older people.

14. Who has reviewed the study?

The study has been reviewed by the Kings Health Partners Gerontology Clinical Academic Group and by the NHS Research Ethics Committee.

15. Contact details

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Tel: 0207 188 8617

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Guy's and St Thomas' NHS
NHS Foundation Trust

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM - PATIENTS

Title of Project: Improving postoperative outcomes in older vascular surgical patients

Name of Researcher: Judith Partridge

Please initial box

1. I confirm that I have read and understand the information sheet dated 1.8.12 (version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that participation is voluntary and that I am free to withdraw at any time without giving reason, and without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from Kings College London, from regulatory authorities or from the NHS Trust, where it is relevant to their taking part in this research. I give permission for these individuals to have access to these records. ☐

4. I agree to take part in the study ☐

----------	----------	----------
Name of patient	Date	Signature

----------	----------	----------
Name of person taking consent	Date	Signature

PARTICIPANT INFORMATION SHEET – Consultees

Study Title: Evaluating the impact of preoperative Comprehensive Geriatric Assessment (CGA) to improve postoperative outcomes in older vascular surgical patients

1. Outline explanation

All patients aged over 65 who are having certain operations at St Thomas' Hospital are being invited to take part in a research study. You have been contacted to help us understand whether the patient would wish to participate. At the moment we do not feel that the patient can fully absorb all the information necessary to make a decision about being in the study. This leaflet explains why we are doing the study and what it will involve. You can ask us any questions you wish about the study. They do not have to take part. It will not affect their care if they are not a part of the research.

2. What is the purpose of the study?

The purpose of this study is to test our theory that care for older patients after surgery can be improved by seeing a healthcare team who specialise in preparing patients for surgery. We will look at how different medical problems can affect people's outcomes after an operation. In particular we will look at how having an operation can affect the way you concentrate and think after surgery. By assessing and treating medical conditions we hope to help patients to recover and get back home again as quickly as possible. If you agree the patient should take part in the study they will be put into one of two groups;

One group (the treatment group) will be given a thorough assessment by a healthcare team specialising in preparing older people for surgery (the POPS team). This usually involves a single visit only to a hospital clinic. The team consists of doctors, nurses, occupational therapists and social workers.

The other group (the control group) will be treated in the usual manner, which is routine care from a nurse in preassessment clinic possibly involving your GP and other services too. This also usually only involves a single visit to a different hospital clinic.

At the moment we only know that the new treatment is as good as the normal treatment in people having this type of surgery. We do not know if it is better. That is why we are going to offer half of the patients the new treatment and half of the patients' current treatment. We will then compare the results. So that we don't influence the results we will put patients into the treatment group or the control group randomly. This is like tossing a coin to decide which group you go into. It means that neither we nor you choose the patients treatment. No experimental medicines will be used in either group. The operation will not be affected at all by taking part in the study.

3. Why have I been invited?

All patients age 65 and over having similar operations to the patient have been invited to take part in the study.

4. Does my relative / friend have to take part?

It is entirely up to you whether you think your relative / friend would wish to be a part of the study or not. It will not affect their care at all whether they take part or not. If you decide that they would wish to be included we will ask you to sign a consent form. Signing the consent form says that you think your relative / friend would want to be included in the study if they were able to answer for themselves. They are free to withdraw from the study at any time. You will not be asked to consent for any type of treatment on behalf of your relative / friend. The process of consenting to take part in this study is different from the process of consent for the operation. The researcher does not have anything to do with the process of consent for the operation.

5. What will happen to me if I take part?

The patient will be invited to attend one of two clinics; either the POPS clinic held at the Older Person's Assessment Unit at Guy's Hospital or the usual preassessment clinic held at St Thomas' Hospital. They will then attend the hospital for their operation in the usual way. Researchers will collect information during these visits on their medical history, medications and time spent in hospital. All information will be kept anonymously.

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We are testing a different way of working or a 'process of care' tailored towards older patients having operations. The study is designed so that patients will not be inconvenienced by taking part in it (for example we do not ask them to attend the hospital more times than they would anyway).

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Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM - CONSULTEES

Title of Project: Improving postoperative outcomes in older vascular surgical patients

Name of Researcher: Judith Partridge

Please initial box

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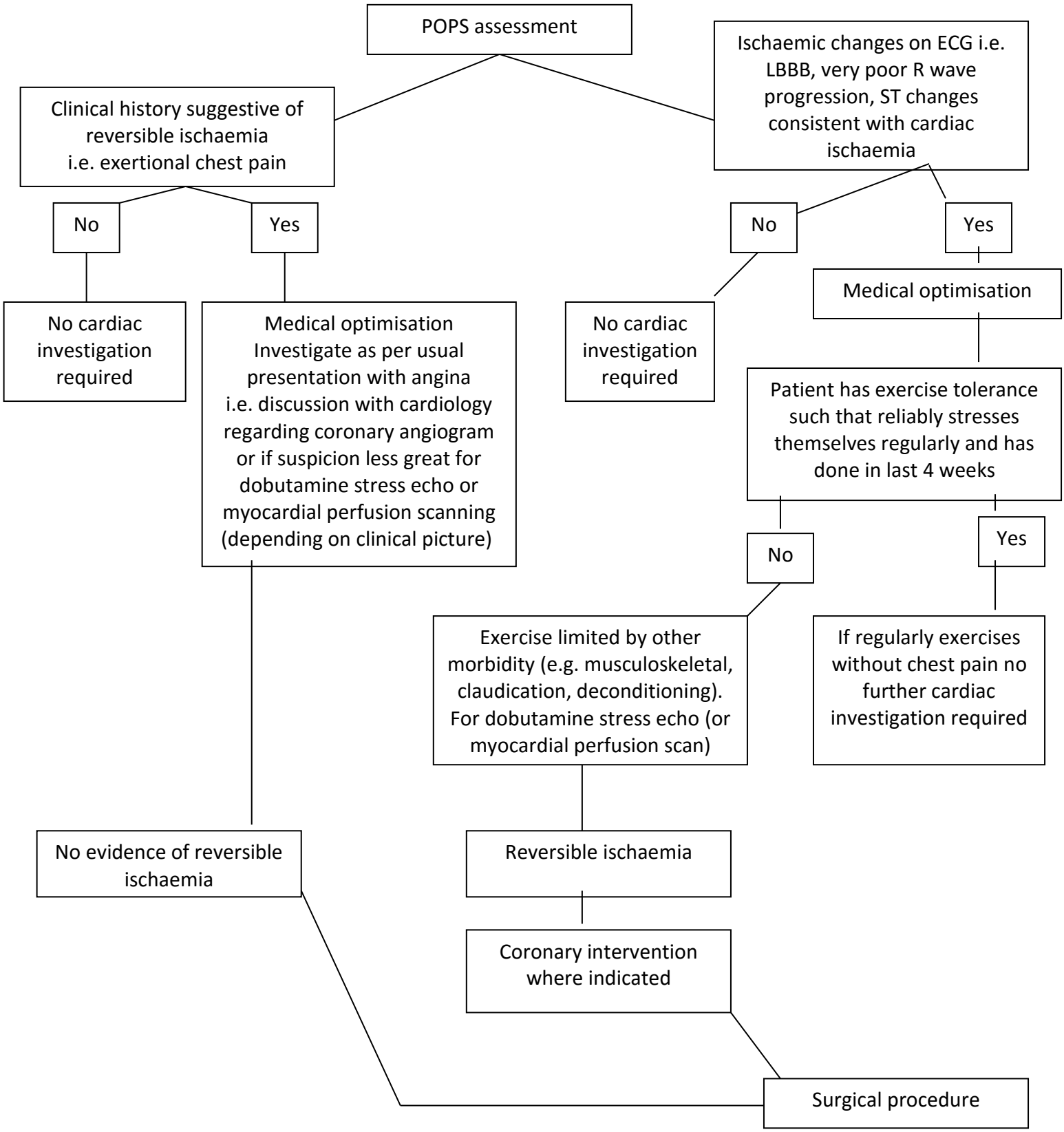
Name of participant

---------- ---------- ----------
Name of consultee Date Signature

---------- ---------- ----------
Name of person taking consent Date Signature

Preoperative cardiac investigation pathway



VPOPS Anaemia Protocol

ASSESSMENT OF ANAEMIA

Full blood count (FBC)
Iron studies
Vitamin B12 measurement
Folate measurement

DEFINITION OF ANAEMIA

Men with haemoglobin < 13g/dL
Women with haemoglobin <12g/dL

NUTRITIONAL CAUSE

Iron <5
(Transferrin saturation <15%)
Vitamin B12 < 35 pmmol/L or 35-50 pmmol/L with raised MMA
Folate < 3.1 ug/L

NON-NUTRITIONAL CAUSE

- Clinical assessment
- Appropriate investigation (as clinically dictated)
- Onward referral (including to rapid access anaemia clinic)

This assessment and management is tailored to the timeframe to proposed surgery

Nutritional deficiency	**Preoperative intervention**	
Timeframe to surgical procedure	*< 2 weeks to surgery*	*≥2 weeks to surgery*
Transferrin saturation < 15%	IV iron	Oral iron (Ferrous fumarate 1 tablet BD)
Vitamin B12 < 35 pmmol/L or 35-50 pmmol/L with raised MMA	IM vitamin B12 loading Maintenance IM 3 monthly thereafter (if oral preparation will not be absorbed e.g. pernicious anaemia, previous gastric surgery, Crohns, atrophic gastritis, medications e.g. metformin etc) Maintenance oral B12 thereafter if dietary cause but no issue with absorption e.g. vegan diet (Note this should be at mega-dose available from health food shops)	
Folate < 3.1 ug/L	Oral folate replacement (5mg folic acid OD)	

FOLLOW UP

If surgery not scheduled for 28 days repeat FBC prior to procedure
Otherwise repeat on day of surgery.

VPOPS Delirium Protocol

ASSESSMENT OF DELIRIUM RISK

Patients will be assessed for delirium risk according to established risk factors for the condition;

- Cognitive impairment
- Previous episode of delirium
- Medical risk factor (e.g. dehydration)
- Medications known to put patients at risk of delirium
- High risk surgical procedure (e.g. open AAA repair)

↓

PROVISION OF INFORMATION TO PATIENT / RELATIVE

- Explanation of delirium
- Provide leaflet on delirium

SHARING OF INFORMATION WITH HEALTHCARE TEAM

- All those with involvement in the patient's ongoing care will be informed of the risk of delirium in order that modifiable factors can be optimised and risk minimised. This includes;
    - Ward nurses
    - Surgical team
    - Anaesthetic team
    - Site management team

↓

***PREOPERATIVE* OPTIMISATION OF DELIRIUM RISK FACTORS**

↓

Risk factors for delirium	**Preoperative optimisation**
Cognitive impairment	Optimise vascular risk factors Refer to cognition protocol Full explanation to patient and relative
Medications	Stop all 'deliriogenic' medications where possible Review need for diuretics (which may put patient at risk from dehydration)
Sensory impairments	Visual – optimise using glasses, referral to optician/ophthalmology, magnifiers as needed Auditory – optimised using hearing aids, referral to audiology/ENT, amplifiers as needed
Dehydration	Stop unnecessary diuretics Educate regarding fluid intake
Constipation	Treat preoperatively according to trust guideline
Pain	Treat preoperatively according to trust guideline Refer to pain team as needed
Frailty	Refer to frailty protocol

↓

ADVICE PROVIDED REGARDING *POSTOPERATIVE* MODIFICATION OF DELRIUM RISK

*signposting to trust delirium guideline

VPOPS Frailty Protocol

ASSESSMENT OF FRAILTY

- Edmonton Frailty Scale
- Gait speed assessment
- Measurement of hand grip strength

→

OPTIMISATION OF ASPECTS OF FRAILTY IDENTIFIED

- Aspects of frailty will be managed according to compensatory strategies or modification
- The specific aspects and approach to optimisation is shown in the table below
- The process of optimisation will vary depending on timeframe to surgical procedure

FRAILTY DOMAIN	SPECIFIC ASPECT OF FRAILTY	COMPENSATION	MODIFICATION
Cognition	*Abnormal clox test*	See cognition protocol	See cognition protocol
Functional independence	*Needs assistance with daily activities*	Arrange care to start on discharge from hospital	Referral to physiotherapist and occupational therapist
Social support	*Has no one to help out at home when required*	Arrange home care /befriending /day centre/ pendant alarm	Referral to social worker for therapeutic interventions
Medication use	*Number of medications* *Forgetting to take medications*	Provision of dosette box Arrange carer to prompt medications	Review / rationalise medications Assess / optimise cognition (see cognition protocol)
Nutrition	*Recent weight loss*	Nutritional supplements Highlight to ward / community dietician *	Assess for underlying cause Dietician, speech and language therapy and occupational therapy
Mood	*Self reported low mood*	MDT input Access to local services (IAPT)	Liaise with GP, Specialist psychiatric services
Continence	*Self reported urinary incontinence*	Provision of pads	Medications, exercise strategies, bladder training regimes * Referral to continence service *
Functional performance	*TUAG > 11 seconds* *Gait speed < 0.6 metres/second* *Grip strength less than norm for age*	Provision of walking aids Provision of equipment to assist patients at home e.g. jar opening devices	Referral for physiotherapy *

*Depending on timeframe to surgical procedure the intervention may consist of highlighting patient to ward team (dietician, therapists) or referral to community teams whilst awaiting surgery.

URN:

Measuring the distress related to delirium – patient questionnaire

Thank you for taking the time to complete this questionnaire. As part of a research project we are trying to find out more about how patients and their families and carers feel about some aspects of having an operation.

We estimate that it will take about 5 minutes to complete this survey. There are no right or wrong answers. Your responses are completely **anonymous** and **confidential.** They will not be seen by your doctors and nurses. We do not need your name.

When you have completed the questionnaire please hand it back to the researcher.

Thank you very much for your help in filling out the questionnaire. If you would like any further information about this research or if you have any questions at all please email judith.partridge@gstt.nhs.uk or call 0207 188 8617

URN:

Delirium Experience Questionnaire - patient

1. Do you remember being confused at all when you were in hospital?

   a) Yes…… ☐

   b) No…… ☐

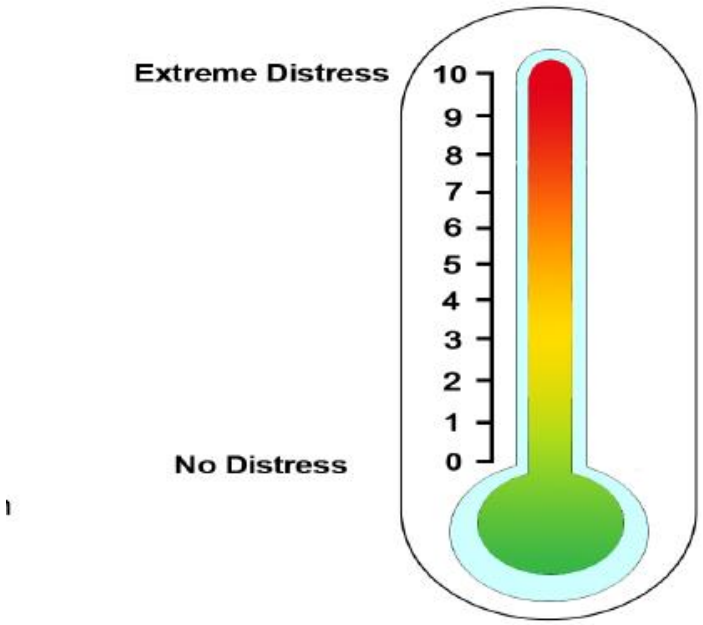
If you answered 'Yes' to Q1 please go on to answer Q3 and Q4.

If you answered 'No' to Q1 please go on to answer Q2 and then Q4.

2. Does it upset you that you can't remember this?

   Please mark how distressed you feel on the thermometer below.

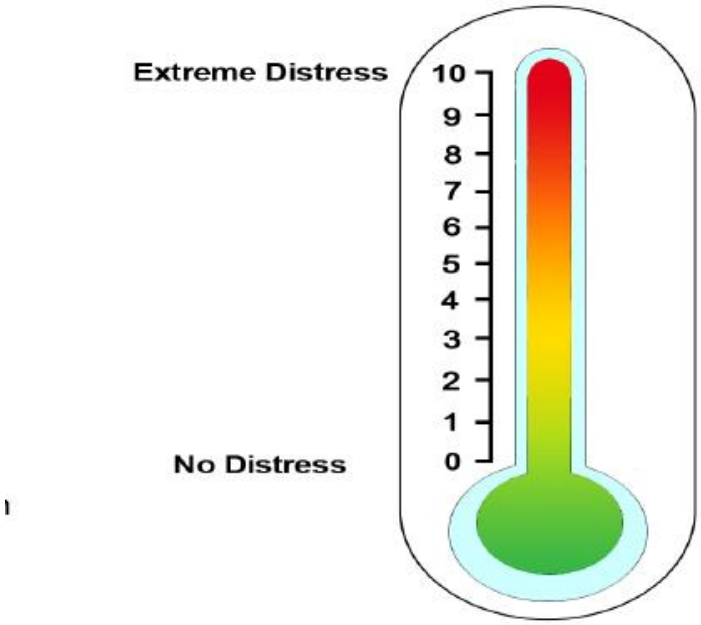
   0 is 'not at all distressed' and 10 is 'extremely distressed'.



3. How distressed were you ***by being confused*** in hospital?

Please mark how distressed you feel related to this confusion on the thermometer below

0 is 'not at all distressed' and 10 is 'extremely distressed'.



4. Were you warned that you might get confused after your operation?

a) Yes…… ☐

b) No…….. ☐

c) I don't remember……... ☐

THAT IS THE END OF THE SURVEY. THANK YOU FOR YOUR TIME IN COMPLETING IT.

Do you have anything else you would like to say about this subject?
Please continue on a separate sheet if necessary.

URN:

Measuring the distress related to delirium – relative / friend / carer questionnaire

Thank you for taking the time to complete this questionnaire. As part of a research project we are trying to find out more about how patients and their families and carers feel about some aspects of having an operation.

We estimate that it will take about 5 minutes to complete this survey. There are no right or wrong answers. Your responses are completely **anonymous** and **confidential.** They will not be seen by your doctors and nurses. We do not need your name.

When you have completed the questionnaire please hand it back to the researcher.

Thank you very much for your help in filling out the questionnaire. If you would like any further information about this research or if you have any questions at all please email judith.partridge@gstt.nhs.uk or call 0207 188 8617

URN:

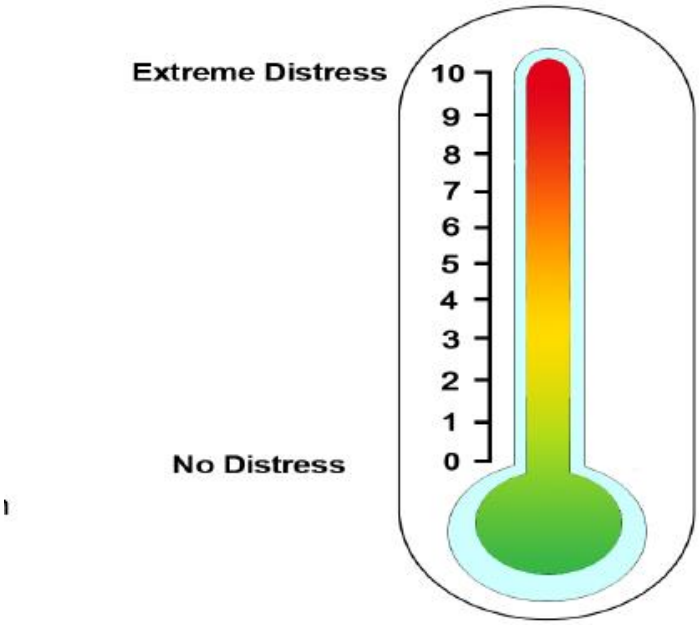
Delirium Experience Questionnaire – relative / friend / carer

1. After their operation your relative / friend became confused. We know that this can be upsetting to see.

   How distressed did it make you feel to see your relative / friend when they were confused?

   Please mark how distressed you feel on the thermometer below.

   0 is 'not at all distressed' and 10 is 'extremely distressed'.



2. Were you warned that your friend/relative may get confused after their operation?

   a) Yes……☐

   b) No……☐

   c) I can't remember……☐

3. Did anybody explain the confusion to you?

d) Yes……☐

e) No……☐

f) I can't remember……☐

3. Please describe your relationship to the patient (e.g. daughter, son, niece, nephew, friend, neighbour etc)

…….

THAT IS THE END OF THE SURVEY. THANK YOU FOR YOUR TIME IN COMPLETING IT.

Do you have anything else you would like to say about this subject?
Please continue on a separate sheet if necessary.

PARTICIPANT INFORMATION SHEET – Patients and relatives/friends

Study Title: Measuring the distress related to postoperative delirium (confusion after an operation) in older surgical patients and their relatives or friends

1. Outline explanation

Patients aged over 65 who become confused after having an operation at Guy's and St Thomas' Hospital are being invited to take part in a research study. We are also inviting their relatives or close friends to be a part of the study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it will involve. This leaflet explains why we are doing the study and what it involves. You can ask us any questions you wish about the study. You do not have to take part. It will not affect your care in any way if you choose not to be a part of the study.

2. What is the purpose of the study?

The purpose of this study is to test our theory that delirium (or an episode of confusion after an operation) can be distressing for patients and for their relatives or friends. We will also examine whether a short questionnaire called the distress thermometer is a good way of measuring this distress. We will look at whether features of the confusion (such as how long it lasts, or how severe it is) make this more or less upsetting for patients and their relatives and friends.

3. Why have I been invited?

We are inviting all patients who have an episode of confusion after an operation to be part of this study. We are also asking their relatives or friends who witnessed the confusion to take part.

4. Do I have to take part?

No, it is entirely up to you whether you choose to be a part of the study or not. It will not affect your care at all whether you choose to take part or not. If you do decide to take part we will ask you to sign a consent form. You are free to withdraw from the study at any time. The process of consenting to take part in this study is different from the process of consent for your operation or any other treatments. The researcher does not have anything to do with the process of consent for your operation or routine treatment.

5. What will happen to me if I take part?

If you would like to take part you will be asked to sign a consent form. You are still free to change your mind about being in the study at any point.

For patients; A researcher will collect information on your medical history, medications and time spent in hospital from your medical records. You will be assessed daily by a researcher to record how severe the confusion (or delirium) is and how long it lasts.

The researcher will then help you to complete some short assessments looking at your memory and your mood. You will be asked to complete a short questionnaire examining your thoughts about being confused for a short time after your operation. If you can't remember being confused then the questionnaire will ask about how distressing you find this lapse in your memory. The questionnaire will take less than 5 minutes to complete. We will ask you to complete the questionnaire twice whilst you are in hospital. These assessments will be performed once the confusion has resolved so that you can fully participate.

Follow-up of participants - 6 and 12 months
At 6 months a distress thermometer will be sent to you with a stamped addressed envelope, asking you to assess your distress (when thinking back to the episode of confusion whilst in hospital). One of the research team will phone you to repeat the HADS questionnaire over the phone.

At 12 months we will contact you for a final time again to complete the distress thermometer postally and one of the research team will phone you to repeat the HADS questionnaire over the phone.

As part of usual care, some patients who become confused after surgery are offered a follow up appointment in a clinic where this confusion (or delirium) can be discussed. If you attend this clinic we will ask you to complete the short questionnaire during that visit. If you do not attend this clinic, you will not be contacted or brought back to the hospital as part of the study to do this.

If during the study your confusion means that you can no longer consent to being part of the study we hope to continue to include you. This is so that we can ask you to complete the questionnaires once your confusion is better.

For relatives / friends; A researcher will give you a short questionnaire to complete. This looks at how distressing it was for you to see your relative or friend confused after their operation. The questionnaire takes less than 5 minutes to complete.

At 6 and 12 months a distress thermometer will be sent to you with a stamped addressed envelope, asking you to assess your distress (when thinking back to the episode of confusion your relative had whilst in hospital).

6. What is the drug or procedure that is being tested?
There is no drug or treatment being used as part of this study. Instead we are examining how you feel about your experiences following your operation so that we can help provide useful information to other patients like you in the future.

7. What are the possible disadvantages and risks of taking part?
There are no specific risks or disadvantages to you in taking part in the study. Your care will not be affected at all whether you choose to take part or not. If you are distressed and need further support the researchers will provide written material and can refer you to the delirium follow up clinic.

8. What are the possible benefits of taking part?
There may be benefits for you in having the chance to discuss your experience of confusion whilst in hospital. Some patients and relatives have told us that they found this a useful experience. The information collected in the study will be used to help improve the outcomes of people like you having operations in the future.

9. What if new information becomes available?
Because we are not testing a new drug or treatment the study will not need to change if new information becomes available.

10. What happens when the research study stops?
When the research project stops your usual care will continue, as it will have done throughout the project.

11. What if something goes wrong?
You are not at any risk by taking part in this study. If you have a concern about any aspect of this study you should speak to the researcher who will do their best to answer your questions. However if you wish to complain about the way you have been treated as part of the study, the usual NHS complaints service is available to you (Patient Advice and Liaison Service, Guy's and St Thomas' Hospital, 02071883416).

12. Is the study confidential?
All the data we collect from you and your medical notes is confidential. We will not use your name or other information that could identify you when the results are analysed.

13. What will happen to the results of the research study?
The results of the study will be presented to other health professionals at meetings and through publishing articles in journals. You will not be identified in any report or publications. Sometimes when we write reports we include quotations that patients or relatives have given us as part of the study. If we use quotations they are always fully anonymised and so cannot be traced back to the person giving the quotation. If you are interested in the results of the study once it has finished you can contact the researcher who can give you a lay summary of the results. You can use the contact details below to do this if you wish to. This study will form part of a PhD.

14. Who is in charge of the research and how is it funded?
The research has been funded by Age UK – Research into Ageing. The researchers and supervisors are NHS doctors and nurses specialising in the healthcare of older people.

15. Who has reviewed the study?
The study has been reviewed by the Kings Health Partners Gerontology Clinical Academic Group and by the NHS Research Ethics Committee.

16. Contact details

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Tel: 0207 188 8617
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Guy's and St Thomas' NHS
NHS Foundation Trust

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM – PARTICIPANTS (patients & relatives/ friends)

Title of Project: Measuring the distress related to delirium in older surgical patients

Name of Researcher: Judith Partridge

Please initial box

1. I confirm that I have read and understand the information sheet dated 10.02.2014 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from Kings College London, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the study ☐

| --- | --- | --- |
| Name of participant | Date | Signature |

| --- | --- | --- |
| Name of person taking consent | Date | Signature |

PARTICIPANT INFORMATION SHEET – Consultees

Study Title: Measuring the distress related to postoperative delirium (confusion after an operation) in older surgical patients and their relatives and friends

1. Outline explanation

Patients aged over 65 who become confused after having an operation at Guy's and St Thomas' Hospital are being invited to take part in a research study. We are also inviting their relatives or close friends to be a part of the study.

You have been contacted to help us understand whether the patient would wish to participate. At the moment we do not feel that the patient can fully absorb all the information necessary to make a decision about being in the study. This leaflet explains why we are doing the study and what it will involve. You can ask us any questions you wish about the study. They do not have to take part. It will not affect their care in any way if they are not a part of the research.

2. What is the purpose of the study?

The purpose of this study is to test our theory that delirium (or an episode of confusion after an operation) can be distressing for patients and for their relatives or friends. We will also examine whether a short questionnaire called the distress thermometer is a good way of measuring this distress. We will look at whether features of the confusion (such as how long it lasts, or how severe it is) make this more or less upsetting for patients and their relatives and friends.

3. Why has my relative / friend been invited?

We are inviting all patients who have an episode of confusion after an operation to be part of this study. We are also asking their relatives or friends who witnessed the confusion to take part.

4. Does my relative / friend have to take part?

No, it is entirely up to you whether you think your relative / friend would wish to be a part of the study or not. It will not affect their care at all whether they take part or not. If you decide that they would wish to be included we will ask you to sign a assent form. Signing the form says that you think your relative / friend would want to be included in the study if they were able to answer for themselves. They are free to withdraw from the study at any time. You will not be asked to consent for any type of treatment on behalf of your relative / friend. The process of consenting to take part in this study is different from the process of consent for the operation. The researcher does not have anything to do with the process of consent for the operation or routine treatment.

5. What will happen to my relative / friend if they take part?

After you have signed the form you are still free to change your mind about your relative or friend being in the study at any point.

For patients; A researcher will collect information on your medical history, medications and time spent in hospital from your medical records. They will be assessed daily by a researcher to record how severe the confusion (or delirium) is and how long it lasts.

The researcher will then help them to complete some short assessments looking at their memory and their mood. They will be asked to complete a short questionnaire examining their thoughts about being confused for a short time after their operation. If they can't remember being confused then the questionnaire will ask about how distressing they find this lapse in their memory. The questionnaire will take less than 5 minutes to complete. We will ask them to complete the questionnaire twice whilst they are in hospital. These assessments will be performed once the confusion has resolved so they can fully participate.

Follow-up of participants - 6 and 12 months

At 6 months a distress thermometer will be sent to your relative with a stamped addressed envelope, asking them to assess their distress (when thinking back to the episode of confusion whilst in hospital). One of the research team will phone them to repeat the HADS questionnaire over the phone.

At 12 months we will contact them for a final time again to complete the distress thermometer postally and one of the research team will phone to repeat the HADS questionnaire over the phone.

As part of usual care, some patients who become confused after surgery are offered a follow up appointment in a clinic where this confusion (or delirium) can be discussed. If the patient attends this clinic we will ask them to complete the short questionnaire for a final time. They will not be contacted or brought back to the hospital as part of the study to do this.

6. What is the drug or procedure that is being tested?

There is no drug or procedure being used as part of this study. Instead we are examining how people feel about their experiences following an operation so that we can help provide useful information to other patients like your friend / relative in the future.

7. What are the possible disadvantages and risks of taking part?

There is no risk to your relative / friend in taking part in the study. Their care will not be affected at all whether they take part or not. If your relative is distressed and needs further support the researchers will provide written material and can refer them to the delirium follow up clinic.

8. What are the possible benefits of taking part?

There may be benefits for your friend / relative in having the chance to discuss their experience of confusion whilst in hospital. Some patients and relatives have told us that they found this a useful experience. The information collected in the study will be used to help improve the outcomes of people like your friend /relative having operations in the future.

9. What if new information becomes available?
Because we are not testing a new drug or treatment the study will not need to change if new information becomes available.

10. What happens when the research study stops?
When the research project stops usual care continues as it will have done throughout the project.

11. What if something goes wrong?
Because we are not changing any treatment at all your relative / friend is not at any risk of harm as a result of taking part in the project. If you or the participant has a concern about any aspect of this study you should speak to the researcher who will do their best to answer your questions. However if you or they wish to complain about the way they have been treated as part of the study, the usual NHS complaints service is available to you (Patient Advice and Liaison Service, Guy's and St Thomas' Hospital, 02071883416).

12. Is the study confidential?
All the data we collect from the participants and from the medical notes is confidential. We will not use their name (or your name) or other information that could identify you or the patient when the results are analysed.

13. What will happen to the results of the research study?
The results of the study will be presented to other health professionals at meetings and through publishing articles in journals. Participants will not be identified in any report or publications. Sometimes when we write reports we include quotations that patients have given us as part of the study. If we use quotations they are always fully anonymised and so cannot be traced back to the person giving the quotation. If you or your relative / friend are interested in the results of the study once it has finished you can contact the researcher who can give you a summary of the results. You can use the contact details below to do this if you wish to. This study will form part of a PhD.

14. Who is in charge of the research and how is it funded?
The research has been funded by Age UK – Research into Ageing. The researchers and supervisors are NHS doctors and nurses specialising in the healthcare of older people.

15. Who has reviewed the study?
The study has been reviewed by the Kings Health Partners Gerontology Clinical Academic Group and by the NHS Research Ethics Committee.

16. Contact details

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Email: judith.partridge@gstt.nhs.uk

Guy's and St Thomas' NHS
NHS Foundation Trust

Centre Number:
Study Number:
Patient Identification Number for this trial:

ASSENT FORM - CONSULTEES

Title of Project: Measuring the distress related to delirium in older surgical patients

Name of Researcher: Judith Partridge

Verbal consent obtained by: **Date:**

Please initial box

1. I confirm that I have read and understand the information sheet dated 10.02.2014 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that participation is voluntary and that the participant is free to withdraw at any time without giving reason, and without their medical care or legal rights being affected. ☐

3. I understand that relevant sections of the participant's medical notes and data collected during the study may be looked at by individuals from Kings College London, from regulatory authorities or from the NHS Trust, where it is relevant to their taking part in this research. I give permission for these individuals to have access to these records. ☐

4. I agree that the participant can take part in the study ☐

Name of participant

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Name of consultee Date Signature

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Name of person taking assent Date Signature